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PARTICIPANT INFORMATION SHEET: RAB001

A study to assess a new candidate rabies vaccine in healthy adults

A phase I clinical trial to determine the safety and immunogenicity of the candidate rabies vaccine ChAdOx2 RabG in UK healthy adult volunteers

We would like to invite you to consider participating in this study. The first page of this information sheet sets out a brief summary. The rest of the document provides more detail. You can ask us for more information at any point.

Summary:

Rabies kills many people every year. Although there are existing vaccines, they are expensive and require multiple doses. We are testing a new rabies vaccine called 'ChAdOX2 RabG', which is intended to be cheaper and require only a single dose. This study is the first time that ChAdOX2 RabG vaccine has been tested in humans. The study will test the safety of the vaccine and measure the immune responses it creates.

The first part of the study involves receiving a single dose of this vaccine and returning for 5 further clinic visits over 8 weeks. If you choose, you may take part in the optional second part of the study where you will be invited back one year later to receive a full course of the currently available rabies vaccine. Participation is voluntary and you are free to change your mind and withdraw at any time.

Who can take part?:	Healthy adult volunteers aged 18-65
Number of study visits:	6 (10 if you participate in the optional additional follow-up)
Study Duration:	8 weeks (56 weeks if you participate in the optional additional follow-up)
Maximum Compensation:	£335 (£605 if you participate in the optional additional follow-up)
Benefits of participation:	Volunteers completing the optional additional follow-up will receive a full course of the current rabies vaccine.
Risks of participation:	We expect side effects to be similar to those of similar vaccines i.e. usually mild. See below for full details. The study does not involve any risk of developing rabies at all.

The rest of this document covers the above areas in more detail, plus additional areas such as how we will protect your personal information, what to do if you have any problems, and where to get more information or make a complaint.

Before you make a decision regarding your participation in this trial, it is important you take the time to understand why the research is being done and what it would involve. Please read the following information carefully and discuss it with friends, relatives and your General Practitioner (GP) if you wish.

Please ask us if there is anything that is not clear, or if you would like more information. Take time to decide whether or not to take part.

What is the purpose of this trial?

Rabies is a nearly 100% fatal disease caused by the rabies virus. Rabies is spread to humans when they are bitten by infected animals, mainly dogs. Rabies is rarely found in North America and Europe but it is a large problem in many other countries. 95% of cases occur in Africa and Asia where the most affected are poorer, rural populations in areas where access to healthcare is limited. Every year 60,000 people die worldwide due to rabies, with most cases occurring in children under 15 years, who are particularly at risk of animal bites.

Vaccines against rabies have existed for many years which, if given correctly, can fully protect people against the disease. However, the currently available vaccines have several limitations. They are too expensive to use in large scale preventative vaccine programmes; are difficult to manufacture, leading to global shortages; and repeated doses must be given over 3 to 4 weeks for the vaccine to be effective. If an unvaccinated person is infected with rabies virus, they will die in almost 100% of cases, unless they receive an intensive "post-exposure" vaccine regime soon after they are exposed.

The purpose of this study is to test a new vaccine against rabies called ChAdOx2 RabG in healthy adult volunteers in the UK. This study will be the first time this vaccine has been given to humans and will enable us to assess:

1. The safety of the vaccine
2. The immune response to the vaccine

We will do this by recruiting 12 people to each receive a single administration of the rabies vaccine being tested. We'll first recruit and vaccinate volunteers at a lower dose before moving to a medium and then higher dose in a stepwise fashion. We will carry out blood tests and collect information on possible symptoms from volunteers during follow up visits after the vaccination.

What is the vaccine being tested?

The vaccine being tested in this trial consists of a virus (ChAdOx2), which is a weakened version of a virus called a *chimpanzee adenovirus (ChAd)* that has been genetically altered to make it impossible for it to grow in humans. We have added a single gene from the rabies virus called *rabies glycoprotein* (RabG) to the weakened ChAdOx2 virus. RabG is an essential component of the rabies virus that it requires to cause disease. By vaccinating people with ChAdOx2 RabG vaccine we hope people will make an immune response against RabG that would protect them from rabies.

Until now, the ChAdOx2 RabG vaccine has only been tested on laboratory mice and this is the first time that the vaccine will be given to humans. For this reason, the doses given to the first participants will be low. If the lower dose is well tolerated then the next group of participants will receive an increased dose in a step-wise fashion. Although this will be the first time ChAdOx2 RabG has been given to people, there is some experience with similar *chimpanzee adenovirus* based vaccines in humans from other clinical trials (see under "Are there any risks from taking part in the trial?" for further details). The vaccine will be injected into the muscle around the shoulder region of your non-dominant arm (i.e. your left arm if you are right-handed); which is the most commonly used way of giving vaccines.

After volunteers have been given the ChAdOx2 RabG vaccine, we will invite them to return one year later to receive a full course of one of three approved rabies vaccine, either: Rabies Vaccine BP, Rabipur or Verorab. These are the currently available vaccines that a GP or a travel clinic would use and will be given in the standard way that they are administered to prevent rabies, which is 3 doses over 3 to 4 weeks. If you go through with this we will inform your GP that you have received a full course of rabies vaccines.

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 for a safety follow up.

Can I take part?

In order to be involved in the study **you must**:

- Be a healthy adult aged between 18 and 65 years.
- Be able and willing (in the Investigator's opinion) to comply with all study requirements.
- Allow the Investigators to discuss your medical history with your GP.
- Practice continuous effective contraception for the duration of the study (women only).
- Refrain from blood donation during the course of the study.
- Tell us about any vaccinations you may have received recently or are expected to receive in the near future.

You **cannot** participate in this study if you have/are:

- Participated in another research study in the last 30 days.
- Planning to participate in another research study at the same time as this study.
- Received any doses of any rabies vaccines in the past.
- Received any investigational vaccines in previous clinical trials that may impact on the results of this study (i.e. any adenovirus vectored vaccines).
- Received immunoglobulins and/or any blood products (such as a blood transfusion) in the 3 months preceding your involvement in this trial.
- Any bleeding, immunological or neurological disorders which may affect safety or responses to vaccines.
- Pregnant, breast feeding or intend to become pregnant during the study.
- Severe allergic reaction to a vaccination.
- History of allergic disease or reactions likely to be exacerbated by any component of the vaccine.
- History of cancer.
- History of a serious psychiatric condition that may affect participation in the study.
- Any other serious long-term illnesses requiring hospital follow-up.
- 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 drugs at any time in the last 5 years.
- You have hepatitis B, hepatitis C or HIV infection.
- You are likely to require a currently available rabies vaccination during the core 8 week study period due to planned travel to an area where rabies is common AND you would be at risk of rabies exposure or due to planned work during the study where rabies vaccination is usually advised.

FOR OPTIONAL FOLLOW-UP INVOLVING CURRENTLY AVAILABLE RABIES VACCINE ONLY:

- Receipt of rabies vaccine, outside of the study procedures, at any time before the extended 1 year follow-up period
- History of allergic reactions to any of the following antibiotics: amphotericin B, chlortetracycline, neomycin, polymyxin, streptomycin, or to any antibiotics of the same groups as those listed, will exclude you from receiving one or more of the 3 currently available rabies vaccines. You may still be able to receive one of the other currently available rabies vaccines.

Mild conditions which are well-controlled, would not automatically exclude you from participating. 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.

You must be able to comply with all of the trial requirements and be able to attend all of the follow up visits.

How is the trial going to work?

For this trial we plan to recruit 12 people. All participants will receive one dose of the ChAdOx2 RabG vaccine only. This will either be at a lower, medium or higher dose. We will first vaccinate 3 people at the low dose and assess them for side effects. If they tolerated the vaccine well, then we will allocate the next 3 volunteers to receive the medium dose. Similarly, if the medium dose is well tolerated then we will step up to the higher dose and vaccinate 6 people at that dose. The groups are shown below:

- Group 1 (3 volunteers): ChAdOx2 RabG 5×10^9 viral particles
- Group 2 (3 volunteers): ChAdOx2 RabG 2.5×10^{10} viral particles
- Group 3 (6 volunteers): ChAdOx2 RabG 5×10^{10} viral particles

After the vaccines are given, we will bring back volunteers to 5 follow up visits over 8 weeks in order to check whether they had any reactions, record their vital signs and take blood tests to check the vaccine safety and immune response. We also ask volunteers to complete an electronic symptom diary to record any symptoms or illnesses following vaccination.

One year after volunteers have received the ChAdOx2 RabG vaccine, they will be invited back to receive a full course of a currently available rabies virus over 3 weeks. This part of the study is optional.

A second optional part of the study will involve the collection of 5mL (a teaspoon) of saliva at each visit. This is unconnected to our rabies vaccine, but will allow us to do a pilot study which may assist the future development of vaccines against two other viruses (Epstein Barr virus and cytomegalovirus). These viruses are related to the chickenpox virus and are similar to it in certain ways: firstly, once you are infected you carry the virus for life, and secondly, most people in the UK are infected without any serious consequences. They can however cause more serious problems for some people. We want to measure the levels of these viruses in saliva, and how this changes over time.

The study will not expose volunteers to rabies virus, Epstein Barr virus or cytomegalovirus.

What will happen if I decide to take part?

Screening Visit – *2 hours (Review participant information sheet with an investigator, 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, you will need to attend an approximately two-hour screening visit up to 3 months before the vaccination day. All study visits will take place at the Centre for Clinical Vaccinology and Tropical Medicine (CCVTM).

At the screening visit you will be met by one of the Investigators who will go through this information sheet with you to ensure you understand what to expect by taking part, the risks involved and what side-effects you might expect to experience. You will receive full and comprehensive answers to any questions you may have.

Once you are happy that you understand what the trial involves, and the Investigator is happy that you have understood everything, you will be asked to sign a consent form which will then be photocopied and given to you to keep.

Once you have signed the appropriate forms, the Investigator will go through a few questions for administrative purposes. 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.

Blood tests will be carried out which include tests for anaemia and tests to see how your liver and kidneys are functioning. We will test you for HIV, Hepatitis B and Hepatitis C viruses. In the event of you testing positive for 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. You will also be asked to provide a urine sample at this visit. Women will also have a urine pregnancy test performed.

Vaccination Visit – *2.5 hours (vital signs, blood test, urine pregnancy test, receive vaccine, 1 hour observation in clinic after the vaccine)*

If you qualify to be in the trial after the screening visit we will arrange a morning for you to attend to receive the ChAdOx2 RabG vaccine (Day 0). You will be asked a few questions to check there have been no new problems since your screening. Your blood pressure, pulse and temperature (vital signs) will be checked and blood samples taken. All women will have a urinary pregnancy test before vaccination.

The ChAdOx2 vaccine will be given on that day as an injection into your (non-dominant) upper arm and the vaccine site will be covered with a dressing. We will need to keep an eye on you in the waiting room of the department for 1 hour after the vaccine. After this period, your vital signs will be checked 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*

During the vaccination visit you will be given a symptom E-diary account as well as an oral thermometer and tape measure. You will be asked to record any symptoms you may experience and your temperature, daily, 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.

Follow up Visits – *15 to 30 minutes (vital signs, blood tests, check for side effects or new health problems)*

After you have received the vaccination, you will attend for several short follow up visits (see diagram below). The first visit takes place two days after vaccination to check if you are experiencing any problems after the vaccine, review your injection site, check your E-diary and have a blood test done. There will be further follow-up visits at 7 days, 14 days, 2 weeks, 4 weeks and 8 weeks after vaccination. 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. You are considered to be enrolled in the trial until you have completed your last visit.

We may ask to photograph your vaccination site(s) and you can choose whether or not to agree to this when you sign the consent form. 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.

There are two additional, optional parts of the study you may choose to take part in. You may choose to take part in both, either one, or neither.

OPTIONAL: Saliva samples (no extra visits)

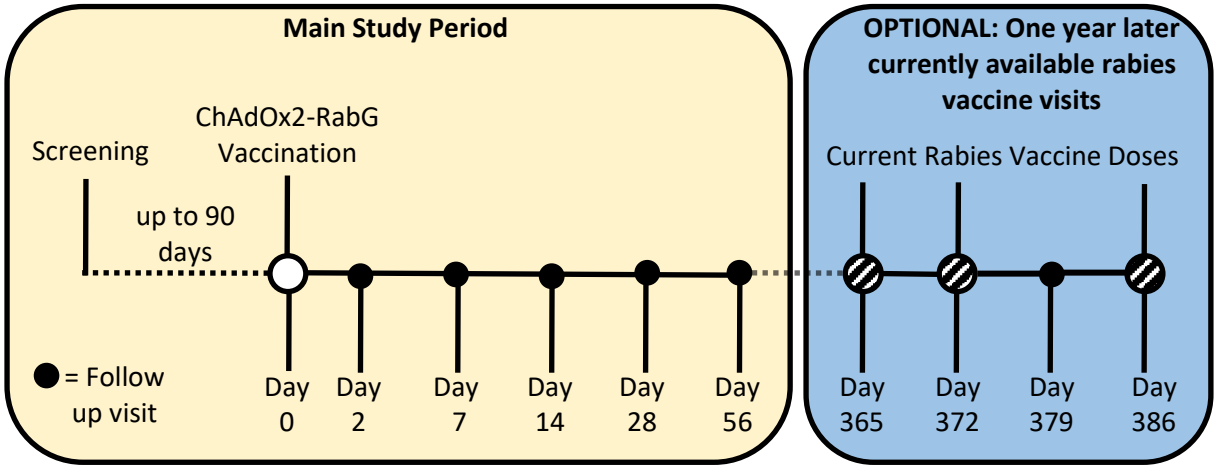
If you are willing to donate saliva samples for this additional part of the study, at each visit we will ask you to rinse your mouth with a teaspoonful of drinking water and spit into a tube.

OPTIONAL: Return after 1 year to receive approved rabies vaccine – *3 doses over 3 weeks plus one follow up visit*

The main trial period will last from your vaccination (day 0) until your follow up visit 8 weeks later. We would also like to invite you back approximately 1 year after your ChAdOx2-RabG vaccine to receive a full course of a currently available rabies vaccine. We hope this will give us further information about your immune response to rabies vaccines. We will give you one of 3 currently available rabies vaccines (Rabies Vaccine BP, Rabipur or Verorab). These have different manufacturers but are similar to each other and are the vaccines that are available for travellers in the UK. This part of the trial is optional and you may choose to not take part. If you do opt for this, you would receive a standard course of the approved vaccine which involves receiving 3 dose of vaccine over 3-4 weeks, as well as attending for an extra visit in between doses.

Length of research

If you choose to take part in the optional 1 year visits to receive an approved rabies vaccine you will be involved in the study for approximately 1 year and 1 month. If you choose not to take part in this you will be involved in the study for approximately 8 weeks.



Considerations before taking part in this study

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

Private Insurance:

If you have private medical insurance or travel insurance, participation in a trial will often not affect your cover for any conditions unrelated to the trial, but to be certain you must tell your insurer you are planning to participate.

Contraception: It is currently unknown whether the vaccine being tested is safe during pregnancy. For this reason, it is important that all women use adequate contraception throughout the trial period, i.e. approximately 12 months. This will be discussed with you at the screening visit. If you were to become pregnant during the trial you must tell us immediately and you will be withdrawn from the study, although we will ask to follow you up for safety reasons. Male participants with female partners are not required to use barrier methods for the purposes of contraception, as the risks of vaccine excretion are negligible. Female volunteers that exclusively have female sexual partners are not required to use contraception.

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. 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. The total amount we will take over the initial 8 week trial period is 284ml. For volunteers that attend for the optional approved vaccine one year later the total volume they will donate over the entire study will be 484ml. These are small amounts of blood that will be well tolerated by healthy adults and are much less than volumes donated by regular blood donors over the same period.

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, potentially including producing monoclonal antibodies, are done at most of the visits.
- The volume of blood taken at each visit ranges from 5 to approximately 60mL (four tablespoons).

The blood samples we collect will be stored after testing, and may be used in future research. Samples will be de-identified and you can request that your samples are destroyed at any time. You will be asked to consent specifically for blood to be stored.

If abnormal results or undiagnosed conditions are found in 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.

2. ChAdOx2 Vaccination Side Effects

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 this vaccine is in a very early stage of development and has not been tested in humans before this trial. 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.

Although the ChAdOx2-RabG vaccine is being tested for the first time here, a similar ChAdOx2 viral-vector-based vaccine has already been administered to 12 people in a different clinical trial as of May 2019. This was at the same 3 doses selected for this trial and was well tolerated by those volunteers. Most had either no symptoms or mild symptoms on the evening of the vaccination that resolved in one to three days and did not disrupt their normal daily activities e.g. going to work. The most severe reaction was a moderate feeling of feverishness and moderate pain at the injection site, both resolving within days.

Additionally, vaccines based on the (similar) ChAdOx1 viral vector have been given to over 200 people and other types of chimpanzee adenovirus viral vector to over 1000 people in several clinical trials. We can predict from these 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 are expected to resolve.

a) Local Reactions

You may experience some discomfort at the injection site as the vaccination is given. This usually gets better in 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.

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 kept in the clinic room 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 (GBS). 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 chimpanzee adenovirus based vaccines.

With any new medicine or vaccine that is early in development there is always a possibility of an unpredicted and 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 too.

3. Side effects from the currently available rabies vaccine (only if you choose the option to receive this)

The currently available rabies vaccines we will use at the optional 1-year follow-up have the potential to cause side effects. The following have been observed to occur with these vaccines:

Very common (these may affect more than 1 in 10 people): Headache, Dizziness, Rash, General discomfort, Fatigue, Weakness, Fever

Common (these may affect up to 1 in 10 people): Swollen glands, Decreased appetite, Nausea, Vomiting, Diarrhoea, Stomach pain/discomfort, Hives, Muscles pain, Joint pain

Rare (these may affect up to 1 in 1,000 people): Allergic reactions, pins and needles or tingling sensations, Sweating, Chills

Very Rare: In exceptionally rare cases, reports of Guillain-Barré syndrome, inflammation of the brain and serious allergic reactions have been linked to rabies vaccines. It is highly unlikely you would experience these side effects.

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 improved vaccine against Rabies. If you decide to continue the study until the optional approved rabies vaccination year follow up, then you will receive a full course of the rabies vaccine.

What if you are bitten by an animal and think you have been exposed to rabies after the trial?

If, in the future, you think you have been exposed to rabies through an animal bite you should seek immediate medical attention. The treatment you would receive depends on whether you had a full course of currently available rabies vaccine before this. If you *only* had the ChAdOx2 RabG vaccine prior to a rabies exposure then you should be treated like you have *not* previously been vaccinated against rabies (i.e. according to local guidelines, so in the UK after a severe bite you would have an immediate rabies immunoglobulin injection and five post-exposure rabies vaccine doses). The reason for this is we do not know yet whether ChAdOx2 RabG will be an effective vaccine.

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 **£605** depending on the exact number of visits attended and whether any repeat or additional visits are necessary. If you choose to opt out of the one year follow up vaccinations you will instead receive **£335** compensation.

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). For participants taking part in the optional one year follow up vaccinations, you will receive two payments; one within six weeks of completing the first 8 weeks of the trial, and a second within six weeks of your completion of the optional follow-up period. 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 vaccinetrials@ndm.ox.ac.uk. 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, government regulatory agencies and the Sponsor (University of Oxford), who can ask to assess the trial data. Responsible 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.

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 CCVTM – Churchill Hospital, 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?

We will be using information from you and your medical records in order to undertake this study. Research is a task that we perform in the public interest. The University of Oxford, as sponsor, is the data controller. This means that we, as University of Oxford researchers, are responsible for looking

after your information and using it properly. We 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. For effective vaccines that may be licensed, we may store research data securely at the University of Oxford for at least 15 years after the end of the study, subject to adjustments in clinical trials regulations. In addition to the de-identified scientific data, we will also store documents containing personal information that you provide when registering for the trial (including contact details), medical information and signed consent forms during this archiving period.

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 Jenner Institute, personal information and medical information including blood test results may be accessed to avoid unnecessary repetition.

A photocopy of your ID (drivers licence, passport or national ID card) will be taken at the screening visit and retained until the end of the study.

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

Your rights to access, change, or move your personal information may be limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at:

http://www.admin.ox.ac.uk/councilsec/compliance/gdpr/individualrights/

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 CCVTM 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.

Involvement of the General Practitioner/Family doctor (GP)

In order to enrol in 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 inform them about your enrolment and study completion status, so they can update your medical records accordingly.

Prevention of 'Over Volunteering'

Volunteers participating in this study must not be concurrently receiving investigational medications or vaccines in another study at the same time. In order to check this, you will be asked to provide your

National Insurance or Passport number. This will be entered on to a national database which helps prevent volunteers from taking part in too many clinical trials. More information can be found at *www.tops.org.uk*. Your national insurance or passport number is also required to allow processing of compensation payments.

What will happen to any samples I give?

If you consent, some of your leftover blood samples (and saliva, if you provide it) will be stored indefinitely at the Oxford Vaccine Centre Biobank and may be used for further studies of the human body's immune response and/or the vaccines used in this study, and/or your safety. Any such tests will have an appropriate ethical review. Upon your request at any time, your remaining blood samples will be destroyed. Your participation in this study will not be affected by your decision whether to allow storage and future use of your leftover samples. More information around the procedures for long term storage of your samples is available in the Oxford Vaccine Centre Biobank information booklet and you will be asked to sign a separate consent form if you agree to have your samples stored for future use in ethically approved research.

To avoid repeat testing, if you are not enrolled into this study and you apply to enter another study conducted by the Jenner Clinical Vaccine Trials Group based at the CCVTM, 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 and saliva samples will be analysed in the hospital laboratories and Oxford University research laboratories. Other tests to look at the response of your body to the vaccine may be done with collaborating laboratories in the UK and in other countries within and outside Europe. You can choose whether or not to allow the transfer of your samples to collaborating institutions and any samples or data sent to them would be anonymous.

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. Doing this helps us to work out which aspects of the immune response to vaccines are due to genetic differences between individuals. You can opt out of 'genetic tests' if you wish, without any effect on your participation in the trial.

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.

Who is sponsoring, organising and funding the research?

The study is organised and sponsored by the University of Oxford. The study is funded by the UK Medical Research Council. Neither your GP nor the researchers are paid for recruiting you into this study.

In the interest of transparency, the scientist leading this study (Dr Alexander Douglas) wishes you to be aware that there is a possibility that he could benefit financially if the vaccine is successful (because

he is a named inventor on a patent relating to the ChAdOx2 vector). Our main aim, however, is to make the vaccine available at the lowest possible cost in low-income countries.

Who has reviewed the study?

This research has been looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given favourable opinion by South Central Oxford A.

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**:

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