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## PARTICIPANT INFORMATION SHEET: VAC077

### A study to assess safety and immunogenicity of the Pfs25- IMX313/Matrix-M1 vaccine

**A Phase Ia study to assess safety and immunogenicity of the *Plasmodium falciparum* malaria vaccine candidate Pfs25-IMX313 in Matrix-M1 adjuvant in healthy adults living in the UK**

We would like to invite you to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it would involve. Please take time to read the following information carefully and discuss it with friends, relatives and your General Practitioner (GP) if you wish.

- Part 1 tells you the purpose of the study and what will happen to you if you take part.
- Part 2 tells you more information about the conduct of the study.

Please ask us if there is anything that is not clear, or if you would like more information. You will be able to discuss the trial with us if you attend a screening visit, and we're happy to answer queries before this too. Take time to decide whether or not to take part.

#### Part 1

##### Why are we conducting this study?

Malaria is a major global health problem. It is a potentially fatal disease caused by a parasite, which is transmitted to people by mosquitoes. Each year there are more than 200 million cases and over 400,000 deaths worldwide, most of which (61%) occur in children under 5 years old. There is a great need for new ways to reduce the spread of malaria by mosquitoes.

**Pfs25-IMX313/Matrix-M1** is a new 'transmission-blocking vaccine' for malaria. The vaccine aims to cause the body to produce an immune response which blocks the malaria parasite developing in the mosquito, so that when the mosquito next bites, it cannot infect another person with malaria. This means that unlike other vaccines, Pfs25-IMX313/Matrix-M1 does not aim to protect the person being vaccinated from disease but instead to reduce risk of infection to other people. In this way, if effective, a transmission-blocking vaccine could stop onward transmission of malaria and bring down the number of cases in the whole population.

In this study, the Pfs25-IMX313/Matrix-M1 vaccine will be given to people for the first time. The purpose of this study is to assess the safety of Pfs25-IMX313/Matrix-M1, as well as the body's immune response to the vaccine. We will do this by giving volunteers three doses of the vaccine, at four week intervals, doing blood tests and collecting information about any symptoms that occur after vaccination. We plan to recruit a total of 8 volunteers to be vaccinated.

## What will happen if I decide to take part?

This study involves having three doses of the Pfs25-IMX313/Matrix-M1 vaccine and then being followed up with regular clinic visits and blood tests at the Centre for Clinical Vaccinology and Tropical Medicine (CCVTM) clinic in Oxford. You will also be asked to complete a diary, recording any symptoms you experience after each vaccination.

## Do I have to take part?

No. It is up to you to decide whether or not to take part. Your decision not to take part will not result in any penalty, or loss of benefits to which you are otherwise entitled. Even after consenting to take part you are free to withdraw at any time without giving a reason, but you may be asked to return to the clinic for follow up for safety reasons.

The University of Oxford does not urge, influence, or encourage any employees/students of the institution to take part in this research study. Your decision to not participate in the study, or a decision on your part to withdraw from the study, will have no effect whatsoever on your employment/student status at the University.

## Length of research

If you decide to take part in this study, you will be involved in the trial for approximately 8 months.

**In addition to the above, we would like to highlight the following key points we think you should consider before making a decision:**

- **This is the first time this vaccine is being tested in humans**

*The Pfs25-IMX313 vaccine is being given to humans for the first time in this study, therefore, we not yet know the effects of the vaccine. The adjuvant that will be given together with the vaccine, called Matrix-M, has however been administered with other vaccines in previous clinical trials and has been shown to be well tolerated. We expect side effects of the vaccine will be similar to those seen in these previous studies using the same adjuvant, but as this is the first trial to test Pfs25-IMX313/Matrix-M1 vaccine, there is a chance that the effects may be different, or more severe.*

- **Following each vaccination, volunteers are required to attend regular clinic follow-ups and complete a daily diary**

*The vaccine schedule involves three vaccinations, given at approximately 4 week intervals. Following each vaccination, volunteers will be required to fill in an electronic diary every day for 28 days and attend the clinic on days 1, 7, 14 and 28 after each vaccine. In addition, there are 2 further clinic visits after the last dose. Overall, volunteers will be followed for approximately 8 months.*

- **Each clinic visit involves blood tests to assess safety of the vaccine and the body's immune response**

*Blood tests will be taken at each clinic visit to help us assess any side effects of the vaccine and how the body's immune system is responding. The volume of blood taken varies between 10 to 128 ml per visit (equivalent to 1-9 tablespoons), with approximately 972mL taken over the course of the study in total. Due to these regular blood tests, volunteers will be required to refrain from blood donation for the duration of the trial, as donating blood could increase the risk of anaemia.*

- **All volunteers are at risk of developing malaria following vaccination**

*This vaccine is designed to prevent onward transmission of malaria, therefore all volunteers will remain at risk of malaria infection themselves. Therefore, in the future, before travelling to an area where malaria is present, volunteers should always seek and follow health advice about malaria prevention.*

## CONSIDERATIONS BEFORE TAKING PART IN THIS STUDY

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### Am I eligible to be involved in the trial?

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

- Be a healthy adult aged between 18 and 45 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.

### You cannot participate in this study if:

- You have had malaria before.
- You have travelled to a malaria endemic region in the last 6 months or are intending to travel to a malaria endemic region during the time you would be involved in the study.
- You have participated in another research study in the last 30 days.
- You are planning to participate in another study at the same time as this study.
- You have previously received an investigational vaccine likely to impact on interpretation of the trial data.
- You have had immunoglobulins and/or any blood products (such as a blood transfusion) in the 3 months preceding your involvement in this trial.
- You have problems with your immune system.
- You are pregnant, breast feeding or intend to become pregnant during the study
- You are allergic to eggs
- You have a history of allergic disease or reactions to any component of the vaccine
- You have a history of a severe allergic reaction to a vaccination.
- You have a history of 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 25 units of alcohol a week (a pint of beer is 2 - 3 units, a small glass of wine (125mL) 1 unit and a shot of spirits (25mL) one unit).
- You have injected illegal drugs at any time in the last 5 years.
- You have hepatitis B, hepatitis C or HIV infection.

Mild conditions, such as childhood asthma, 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.

**Screening Visit:** This takes place at The Centre for Clinical Vaccinology and Tropical Medicine (CCVTM) at The Churchill Hospital, Oxford and will last approximately two hours. The purpose of the screening visit is

for you to discuss the trial with us and decide if you wish to enter the study. If you decide to participate, you will be asked to sign a consent form and we will check that you are eligible to participate.

*After signing the consent form:*

- You will be asked some medical questions
- A doctor will examine you
- Blood samples and a urine sample will be taken. These tests will need to be normal for you to be enrolled in the study
- All women will have a urinary pregnancy test

Please note – The screening blood tests will look at your blood counts (e.g. to check if you are anaemic), your liver function and your kidney function. We will also test your blood to see if you are infected with hepatitis B, hepatitis C or HIV, as these conditions can affect your body's response to the vaccines we are assessing. If you test positive to any of these, we will let you know and arrange for a repeat test. With your consent we may also report positive results to your GP and offer to refer you for further investigation/treatment.

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

**Private Medical Insurance:** If you have private medical insurance you are advised to contact your insurance company before participating in this trial, as involvement may affect the cover provided.

**Malaria Prophylaxis:** If in future you travel to an area where malaria is common, you should not assume that the experimental vaccines you received in this study will give you any protection against malaria. Even if this vaccine is effective, it is not designed to protect the recipient from malaria infection. Make sure you visit your GP or a travel clinic before travelling to a malaria endemic region and follow their advice on prevention measures.

**Contraception:** It is currently unknown whether the vaccines being tested are safe during pregnancy. For this reason, it is important that all women use adequate contraception throughout the trial. 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.

## THE VACCINE

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### What are the vaccines that are being tested?

Pfs25-IMX313/Matrix-M1 is a '**protein-in-adjuvant**' vaccine, made up of the protein **Pfs25-IMX313** and the adjuvant **Matrix-M1**. This is not a live vaccine and so there is no chance of catching malaria. Vaccinations will be given into the muscle of the upper arm (usually on the non-dominant side, i.e. on the left arm if you are right-handed).

### **Pfs25-IMX313**

The protein Pfs25-IMX313 has two parts: **Pfs25** and **IMX313** which are fused together.

Pfs25 is a protein found on the surface of the *Plasmodium falciparum* malaria parasite as it develops in the mosquito. An effective immune response against this protein could stop the growth of malaria in the mosquito, preventing the parasite from being transmitted by the mosquito to another human.

IMX313 has been added to Pfs25 protein to help 'display' the protein to the body's immune system. Previous laboratory work has shown that IMX313 can increase the immune response.

A similar vaccine to the one we are testing in this study, based on the same fusion of Pfs25-IMX313 has been given to 26 healthy UK adults in a previous trial in Oxford. This was not as a protein vaccine but instead within virus “carriers” that display it to the body’s immune system. Within this vaccination formulation it was found to be safe and well tolerated.

### **Matrix-M1**

Matrix-M1 is a vaccine adjuvant – a substance that helps improve the body’s immune response to a vaccine. Matrix-M1 has previously been given to over 1000 healthy volunteers in other clinical trials and has been safe and well tolerated. This includes trials of other investigational vaccines for malaria.

### **Pfs25-IMX313/Matrix-M1**

As outlined above, although there is limited safety data from the similar vaccine to the protein (Pfs25-IMX313) that we have tested previously, and more extensive safety data on the adjuvant (Matrix-M1), neither the Pfs25-IMX313 protein vaccine or the combination of Pfs25-IMX313 with Matrix-M1 has been given to anyone before this study. So this a “first-in-human” trial, the purpose of which is to assess the safety of the combination Pfs25-IMX313/Matrix-M1 vaccine.

### **What dose of the vaccine is being tested?**

The optimal dose of the Pfs25-IMX313/Matrix-M1 vaccine is not yet known. The aim of this initial study is to assess the safety of the Pfs25-IMX313 protein at a dose of 10µg (micrograms). Therefore, all volunteers will receive the same dose of the vaccine, at each of the three vaccinations. We will also assess the body’s immune response at this dose. If demonstrated to be safe, a future study will look at the safety and immune response to the vaccine in different doses, with different dosing schedules of the protein.

Based on previous studies, the optimal dose of the adjuvant Matrix-M1 is 50µg. This is the dose that we will be using in this trial, in combination with the Pfs25-IMX313 protein.

The doses and schedule of the vaccine and adjuvant to be given in this study are summarised below:

| Group          | Group size | D0   | D28  | D56  |
|----------------|------------|--|--|--|
| <b>Group 1</b> | 8          | 1 <sup>st</sup> Vaccination:<br>10µg Pfs25-IMX313/<br>50µg Matrix-M1 | 2 <sup>nd</sup> Vaccination:<br>10µg Pfs25-IMX313/<br>50µg Matrix-M1 | 3 <sup>rd</sup> Vaccination:<br>10µg Pfs25-IMX313/<br>50µg Matrix-M1 |

### **What are the expected side effects from this vaccine?**

Once the vaccinations have been given they cannot be undone, so it is important you understand the potential risks of the vaccines before you agree to be involved in the study.

This particular vaccine has not been used in humans before but we do not expect the side effects of this vaccine to be significantly different from previous trials where different protein vaccines have been used with the same adjuvant (Matrix-M). We expect that most symptoms will be mild, but symptoms may also be moderate or severe in how strong they are. All symptoms should resolve completely within a few days.

You may experience any of the following short-lived side effects:

- Injection site pain (most likely mild; however there is a chance this could be moderate or severe in intensity).
- Redness, swelling, itching and warmth at the vaccine site (symptoms are likely to be mild if present; however, there is a chance this could be moderate or severe in intensity).

- A ‘flu-like’ illness within 24 hours of vaccination which usually resolves within 48 hours. (This can include headache, muscle aches, joint aches, feverishness, tiredness, nausea and feeling generally unwell). The majority of general symptoms are likely to be mild but there is a possibility of moderate or severe symptoms occurring.

**It is important to remember this vaccine is being tested in humans for the first time in this trial, so there is a chance you could experience a side effect different in nature, or more severe than those described.**

### Severe Reactions

With any vaccination there is a low risk of serious reactions, which may be related to the nervous system or the immune system. Severe allergic reactions to vaccines (anaphylaxis) are very rare but can be fatal. Doctors qualified in the management of anaphylaxis and appropriate equipment and medication will be present at each vaccination. Reactions in the nervous system are also extremely rare following vaccination, but can cause an illness called Guillain-Barré syndrome. Guillain-Barré syndrome is an illness in which people can develop severe weakness and may be fatal. However, these reactions have not previously been seen with the type of vaccine used in this study. If you experience unexpected symptoms, or become in any way concerned you should contact one of the Investigators (who are available 24 hours a day) using the emergency contact details that you will be given once you have been vaccinated.

### VISITS

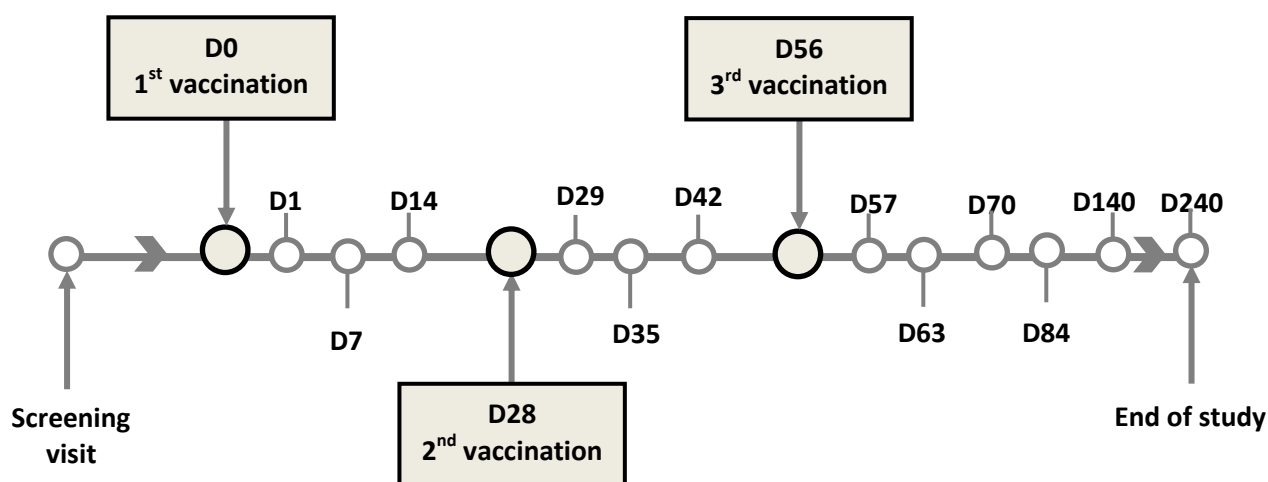
You will receive 3 vaccinations and attend 16 visits in total. All visits will take place at the Centre for Clinical Vaccinology & Tropical Medicine (CCVTM) in Oxford.

#### Number, timing and purpose of visits

Each vaccination is given four weeks apart (on days 0, 28 and 56). Volunteers will be reviewed in clinic the day after each of the three vaccinations and then at one week, two weeks and four weeks post-vaccination. In addition to this there are 2 further clinic appointments, on days 140 and 240 after the third vaccination. This means that the final clinic review will be approximately 8 months after the first vaccine dose.

At each visit we will check your temperature, pulse and blood pressure readings, ask you some medical questions and usually take some blood tests. You may also be examined by a doctor if needed.

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.



## **Vaccinations**

On each vaccination day, we will assess you to check for any new medical problems since your last visit and make sure that you are still happy to go ahead. We will also take some blood tests. All women will also have a urinary pregnancy test. The vaccines will be given into the muscle of your upper arm, usually on the non-dominant side.

After each vaccination, we will ask you to wait in the clinic for 1 hour to check there are no immediate problems. You will be assessed again before leaving and be given a thermometer and tape measure to take away. We will also show you how to use the electronic diary and ask you to record your symptoms and any redness at the vaccination site every day for 7 days after each vaccination. After these 7 days we will just ask you to record if you feel unwell or take any medications over the next 3 weeks.

At the follow-up visits, we may ask to photograph your vaccination site. You will not be identifiable in these photographs and you can choose whether or not to agree to this when you sign the consent form. Photographs may be shown to other professional staff, used for educational purposes or included in a scientific or academic publication.

## **First volunteers**

As this is the first time that the Pfs25-IMX313/Matrix-M1 vaccine is being administered to people, for safety reasons, we will initially vaccinate one volunteer alone. We will then monitor the volunteer until at least 2 days after vaccination. If there are no safety concerns, a further 2 volunteers will be vaccinated, at least an hour apart. One week after the second and third volunteers are vaccinated, we will review all the information on the symptoms the first three volunteers experienced after vaccination. If any side effects experienced are as expected, then the remaining five volunteers will be vaccinated.

You will be able to choose whether you wish to be one of the first three volunteers vaccinated.

## **OTHER INFORMATION**

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### **Blood Tests**

We take blood tests as part of the screening visit and at the study visits in order for us to assess your general health, your immune response to the vaccine and to assess the safety of the vaccines. The volume of blood taken at each visit ranges from 10 to 128 ml. The total volume of blood taken over the course of the study will be approximately 972mL. If you would like them, we can give you the results of your blood tests. De-identified blood samples will be stored after testing, and may be used in future malaria research. You will be asked to consent specifically for blood to be stored and shared with other researchers.

To avoid repeated testing, if you are not enrolled into this study and apply to enter another study conducted by the Jenner Clinical Trials Group based at the CCVTM in Oxford, the screening blood results may be used in that study, where appropriate and with your consent.

### **Abnormal Results**

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.

### **Expenses and Payments**

You will be compensated for travel, time and the inconvenience of blood tests for each visit during the trial, and for attending a screening visit. The approximate total compensation for taking part in this study will be £790. Payment will be made via BACS within six weeks of completing the study.

You will be compensated as follows:

- Screening visit £25 per visit
- Travel expenses: £15 per visit (if travel to the trial site costs more than £15 additional reimbursement may be offered)
- Time required for visit: £20 per hour
- Inconvenience of blood tests: £10 per blood donation

If additional pre-enrolment visits are required (for example, for any repeat blood tests needed due to an abnormal result), you will receive a fixed payment of £10 per visit. You will also receive additional compensation for any extra visits attended during the course of the trial.

If you choose to leave the study early or are withdrawn from the study, you will be compensated according to the length of your participation based on these figures. Please note that if you do leave the study early it can take several weeks for your final payment to be made.

You should note that compensation payments received in this trial may have an impact on your entitlement to benefits.

|                | Time in Trial<br>(approximate) | Maximum<br>number of Visits | Maximum volume<br>of Blood Taken (mL) | Compensation |
|----------------|--------------------------------|-----------------------------|---------------------------------------|--------------|
| <b>Group 1</b> | 8 months                       | 16                          | 972                                   | £790         |

#### **What alternatives are present?**

At present, there is no transmission-blocking malaria vaccine approved anywhere in the world. There are other malaria vaccines in various stages of development. This study may help develop an effective transmission-blocking malaria vaccine.

#### **What are the possible benefits of taking part?**

This study will not benefit you, but the information gained from the study might help to prevent malaria infection and disease in those living in areas where malaria is common and in travellers to those areas.

#### **Will my taking part in the study be kept confidential?**

Yes. All the information about your participation in this study will be kept confidential. The details are included in Part 2.

**This completes Part 1 of the Information Sheet. If the information in Part 1 has interested you and you are considering participation, please continue to read the additional information in Part 2 before making any decision.**



## **Part 2**

### **What if relevant 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 may be asked to sign an updated consent form. On receiving new information, we may consider it to be in your best interests to withdraw you from the 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 study?**

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. Your decision will not result in any penalty, or loss of benefits to which you are otherwise entitled. 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. Similarly, all your data collected up to the point of your withdrawal will be stored, unless you specifically request for it to be destroyed. You are free to request that your blood samples are destroyed at any time during or after the study.

### **What if there is a problem?**

If you are harmed as a result of taking part in this study, the study doctor can advise you of further action and refer you to a doctor within the NHS for treatment, if necessary. The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this trial. NHS indemnity operates in respect of the clinical treatment which may be provided if you needed to be admitted to hospital.

The Investigators recognise the important contribution that volunteers make to medical research, and make every effort to ensure your safety and well-being. In the event of harm being suffered, while the University will cooperate with any claim, you may wish to seek independent legal advice to ensure that you are properly represented in pursuing any complaint. At any time during the study you will be entirely free to change your mind and withdraw from the study. This will not affect your subsequent medical care in any way.

### **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 your local trial team (contact details at the end of this document) or you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 616480 or the head of CTRG, email [ctrig@admin.ox.ac.uk](mailto:ctrig@admin.ox.ac.uk).

### **Will my taking part in this study 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. Responsible members of the University may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations. Any information about you that leaves the clinic will have your name and address removed so that you cannot be identified from it. Your information is stored electronically on a secure server and any paper notes are kept in a locked filing cabinet.

### **Involvement of the General Practitioner/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 whether or not you are finally enrolled in the study, and whether or not you completed the study, so they can update your medical records accordingly.

### **Prevention of 'Over Volunteering'**

Volunteers participating in this study must not be 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](http://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?**

All samples will be stored in a de-identified form. Your study visit blood tests will be analysed in Oxford University research laboratories. Blood tests for your general health will be carried out in the NHS laboratories at Oxford University Hospitals. 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 NHS laboratories or collaborating labs would be de-identified.

If you consent, some of your leftover blood samples will be stored indefinitely at the Oxford Vaccine Centre Biobank and may be used for further related research, including of the human body's immune response and/or vaccine research and/or your safety. Any such future research will have an appropriate ethical review. Upon your request at any time, your remaining blood samples will be destroyed. 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. If you decide not to consent to storage of your samples in the Biobank, these samples will be disposed of at the end of the study. Your participation in this study will not be affected by your decision to allow or not allow storage and future use of your leftover blood samples.

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 second trial you applied for.

### **Will any genetic tests be done?**

Yes. Some blood will be used to look at the pattern of your genes that can affect the immune system (including your 'human leukocyte antigen' [HLA] type). Since these genetic tests are not carried out to look at your general health, you would not be given the results of these tests. You can opt out of 'genetic tests' on the consent form if you wish, without any effect on your participation in the trial.

### **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 for 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.

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/>

### **What happens when the research study stops?**

If you have any queries or concerns once the study is over, please do not hesitate to get in touch with us.

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 anonymised data from this study will be shared with the collaborating partners who are organising and funding this research work, including the Wellcome Trust. 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.

A description of this study will be available on [www.clinicaltrials.gov](http://www.clinicaltrials.gov). This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

### **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.

### **Who is sponsoring, organising and funding the research?**

The study is organised by the University of Oxford. The study is funded by the Wellcome Trust. 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 National Research Ethics Service (NRES) Committee South Central Oxford A and has been given a favourable ethical opinion. A Research Ethics Committee is an independent group of people who review research to protect participants' interests.

**Thank you for reading this information sheet. If you are interested in taking part in the study please contact the study team at your local study site to arrange a screening appointment.**

**Contact details for further information:**

Volunteer Recruitment Co-ordinator

[vaccinetrials@ndm.ox.ac.uk](mailto:vaccinetrials@ndm.ox.ac.uk)

Tel: 01865 611406

CCVTM, Churchill Hospital, Old Road, Headington, Oxford, OX3 7LE