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NRES Committee London- City & East

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PARTICIPANT INFORMATION SHEET: BIO-001 / CVIA 099

Groups 1, 3, 4 and 5

A study to assess the safety and effectiveness of two experimental malaria vaccines

We are inviting 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 involves. Please read the following information carefully. You can discuss it with friends, relatives and your General Practitioner (GP/doctor) if you wish. Take time to decide whether or not you wish to take part.

- **Part 1** tells you the purpose of the study.
- **Part 2** tells you if you are eligible to take part and what will happen if you take part.
- **Part 3** tells you about any possible risks and benefits of taking part.
- **Part 4** tells you more information how the study will be carried out.

Ask us if there is anything that is not clear or if you would like more information. You can ask us any questions at your screening visit. You can also contact us on the email address at the top of the page.

This information booklet has been reviewed by four members of the Oxford Vaccine Centre's patient and public involvement (PPI) team. The PPI team make sure the information is presented in a way that is clear and understandable.

Who can take part?	Healthy adults aged 18-45 (full criteria inside)
What vaccines are being tested?	Malaria vaccines RH5.1 and RH5.2-VLP
Total participants	Approximately 32 participants across groups 1, 3, 4 and 5
Study aims	To test safety and immune responses to these vaccines
Trial site	Centre for Clinical Vaccinology and Tropical Medicine (CCVTM), Churchill Hospital, Oxford, OX3 7LE
Expenses and payment	£1,790 to £1,880
Risks of participation	Short-lived post vaccine symptoms such as arm pain and fever may occur. A full discussion of risks, including potential rare but serious reactions is contained within (page 10). As this is a phase 1 study, we will monitor the safety of all participants closely.
Benefits of participation	Participating in this trial will help our research into the development of a safe and effective vaccine against malaria.
Visit schedule	19 to 20 visits over approximately 1.5 to 2.5 years

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PART 1: THE PURPOSE OF THE STUDY

Why are we conducting this study?

Malaria is a major public health problem. Malaria is an infectious disease caused by a parasite. It is spread by the bite of an infected mosquito. There were around 240 million cases of malaria and 627,000 deaths worldwide in 2020. Most of the deaths are in children under five living in Africa. It is a big problem for those who live in affected areas and for travellers. There is a great need for a safe, effective malaria vaccine. This is because the range of effective medicines for treating malaria is limited and commonly used medicines are becoming less effective. Researchers around the world, including the University of Oxford, have been working on malaria vaccines for many years.

There is currently no widely available and consistently effective vaccine against malaria. We are trying to make a vaccine which is better at preventing serious illness and death.

This study is being done to evaluate an experimental malaria vaccine for its safety. We will also look at the body's immune response to the study vaccines. A different group (Group 2) will look at its ability to prevent malaria illness in a 'blood-stage challenge model'. This is when volunteers are infected with malaria parasites using malaria-infected red blood cells. Groups 1, 3, 4 and 5 will not be infected with malaria in this study.

The vaccines we are testing in this study are called "**RH5.2-VLP**" and "**RH5.1**". They are given with an adjuvant called "**Matrix-M**". An adjuvant is a substance to improve the body's response to a vaccination.

The aim is to use the vaccines and adjuvant to help the body make an immune response against parts of the malaria parasite. This study will assess:

1. The safety of the RH5.2-VLP vaccines in healthy participants.
2. The response of the human immune system to the RH5.2-VLP vaccines.
3. The ability of the RH5.2-VLP vaccine to prevent malaria illness (Group 2 only).

We will do this by giving participants three doses of the study vaccines. We will then do blood tests and collect information about any symptoms that occur after vaccination. We will also expose volunteers in a different group (Group 2) to malaria infection under carefully regulated conditions. We will do this to see if the RH5.2-VLP vaccine is able to control the malaria infection and prevent it from taking hold. This group will receive a malaria infection ("challenge") if the immune response to the RH5.2-VLP vaccine is shown to be strong in the first Group of participants (Group 1). We aim to recruit 8 participants to be vaccinated in each of groups 1, 3, 4 and 5. In total, there will be 56 volunteers in this study.

What are the vaccines being tested?

RH5.1 and **RH5.2-VLP** are based on part of a malaria protein known as RH5. The malaria parasite uses RH5 as a 'key' to get into red blood cells. This is how people get sick from malaria.

RH5.1 is a protein vaccine. Protein vaccines contain small purified protein pieces from the pathogen which have been selected to trigger a strong immune response. RH5.1 has been used in two previous trials and given to over 100 volunteers. It has been shown to be safe and well tolerated in these trials. It has also been shown to make a good immune response and slow down the rate of malaria infection. This was shown in a recent study of healthy UK volunteers who were deliberately infected with malaria after having this vaccine. However, it ultimately doesn't stop the malaria from spreading through the bloodstream.

RH5.2-VLP is a virus-like particle (VLP). VLPs are molecules that closely resemble viruses. However they are non-infectious because they contain no viral genetic material. As VLPs look like viruses they cause

the body to have a strong immune reaction to the vaccine. RH5.2-VLP has not been given to humans before. Other malaria vaccines based on similar VLP technology, such as "RTS,S" and "R21", have been given safely to thousands of people.

Matrix-M has been given to tens of thousands of volunteers in other trials. It has been shown to be safe and well tolerated. This includes trials of vaccines for malaria, COVID-19 and influenza. Matrix-M has now been approved for use in the UK as part of Novavax's COVID-19 vaccine.

By giving people RH5.2-VLP/Matrix-M with or without RH5.1/Matrix-M we hope the body will develop an immune response that is even better than the response seen against RH5.1 in previous studies. The ultimate goal is for a vaccine to help the body prevent the parasite from using the RH5 'key' to get into the blood cells and so stop malaria illness.

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. You are free to withdraw at any time without giving a reason. However, we may ask you to return to the clinic for follow up for safety reasons.

For University of Oxford staff or students: The University does not urge, influence, or encourage you 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.

What will happen if I decide to take part?

This study involves having three doses of an experimental malaria vaccine. This may be RH5.2-VLP, RH5.1 or both. See page 7 for more details about the vaccines each group will receive.

You will be followed up with regular clinic visits and blood tests. Visits will take place at the Centre for Clinical Vaccinology and Tropical Medicine (CCVTM). This is at the Churchill Hospital in Oxford. You will be asked to complete a diary to record any symptoms you experience after each vaccination.

Volunteers in Groups 1 and 3 will be invited to an optional visit. If this applies to you, you will receive another information sheet called "Groups 1 and 3 additional information: Fine needle aspiration".

The CCVTM clinic is wheelchair accessible. If you have other accessibility needs, please contact us to discuss them. We will try to meet your needs wherever possible.

Length of research

You will be involved in the trial for about 1.5 to 2.5 years. You will attend 19-20 visits. However, the majority of visits will be in the first year (see detailed visit schedule on page 8).

PART 2: WHO CAN TAKE PART AND WHAT WILL HAPPEN?

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.
- Able and willing to meet all study requirements.
- Willing to allow the Investigators to discuss your medical history with your GP (General Practitioner).
- Willing not to donate blood during the study.

You cannot take part in this study if:

- You have had malaria before.
- You have travelled to an area with malaria transmission in the last 6 months. Or, you are intending to travel there during the study period.
- You have previously received a malaria vaccine.
- You have had any other vaccine in the past 30 days or plan to have any other vaccine within 30 days of receiving the study vaccines (apart from COVID-19 and flu vaccinations).
- You are taking part in another study using an experimental treatment.
- You have received any other blood products in the last three months. This includes a blood transfusion or immunoglobulins.
- You have problems with your immune system. This includes taking any medication that suppresses your immune system.
- You are pregnant, breast feeding or intend to become pregnant during the study.
- You have a history of allergies or reactions likely to be worsened by any part of the study vaccines.
- You have had an anaphylaxis after vaccination.
- You have a history of cancer. Basal cell carcinoma of the skin and cervical carcinoma in situ are not an exclusion.
- You have a history of a serious mental health condition that may affect your taking part 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 two units, a small glass of wine 1 unit and a shot of spirits one unit.
- You have injected recreational drugs at any time in the last 5 years.
- You have hepatitis B, hepatitis C or HIV infection.
- There are any other reasons that the study doctors think you should not join the study.

Mild conditions do not automatically exclude you from taking part. An example could be childhood asthma which is well controlled. If you are unclear whether you are eligible, you can contact the study team who will be able to advise you.

If enrolled in the study, you may be temporarily excluded from receiving the study vaccine if:

- You are feeling unwell on the day of your vaccination appointment.
- You have a fever (temperature >37.5°C).

In such an event, we will delay your vaccination appointment until at a later date, or withdraw you from the study if more appropriate.

Is there anything else to think about?

Blood Donation

If you are a blood donor, we ask that you do not donate blood during the study period due to the additional blood volume that will be taken during the study.

Pregnancy and Contraception

The potential effect of the vaccine used in this study on an unborn baby is unknown. If you are able to become pregnant then you will be asked to use an effective method of contraception until at least 3 months after your final vaccination. This will be a total of 5 months for Group 1. For Groups 3, 4 and 5 it will be approximately 9 months. Condoms alone are not considered effective enough.

Acceptable forms of contraception include:

- Hormonal contraceptives. This includes the pill, mini-pill, contraceptive injection, implant or transdermal patch.
- Placement of an intrauterine device or intrauterine system. These are also known as the copper coil or hormone coil (e.g. Mirena coil).
- Vasectomy (male sterilisation), if this is your only partner.
- Complete abstinence from any sexual relationships in which you may become pregnant. Periodic abstinence and withdrawal methods are not acceptable.

A pregnancy test will be done at screening and just before each study vaccination. If you become pregnant during the trial, we would not give you any further vaccinations. However, we would like to follow you up for the rest of the study, and with your permission, until the pregnancy outcome, to monitor your and your baby's wellbeing. We would not routinely perform any further blood tests on pregnant volunteers.

Private Insurance

If you have private medical insurance you should contact your insurance company before participating in this trial. Involvement may affect the cover provided.

Malaria Protection

You should not assume that the experimental vaccines you receive in this study will give you any protection against malaria. Make sure you visit your GP or a travel clinic before travelling to an area where malaria is found. You should follow their advice on prevention measures.

What will happen at the visits?

Screening Visit

First we will need to check whether you are eligible to join the study. Following an online pre-screening questionnaire, we will contact you by telephone or email. You will have an opportunity to ask any more questions about the study at this point. We will also arrange for you to attend a screening appointment.

The screening appointment takes place up to 3 months before the study starts. It can last up to two hours. There will be an opportunity for a short break. The purpose of the screening visit is for you to discuss the trial with us and decide if you still wish to take part. If you do, we will ask you to sign a consent form.

After signing the consent form:

- You will be asked some medical questions.
- A doctor will examine you.
- Blood samples will be taken for testing. These test results will need to be normal for you to be enrolled in the study.
- A urine sample will be taken for a pregnancy test if you are able to become pregnant.

The blood tests will look at:

- Your blood count (for example, to check if you are anaemic).
- Your liver and kidney function.
- Whether you have hepatitis B, hepatitis C or HIV. This is because these conditions can affect your body's response to the vaccines we are assessing.

If any of your tests are not normal, we will let you know and arrange for a repeat test. With your consent we may also report any abnormal results to your GP and offer to refer you for further investigation/treatment. If you test positive for Hepatitis B or C, the laboratory is required to notify the UK Health Security Agency of this result.

Some people may test positive for Hepatitis C virus because they have previously taken part in a Hepatitis C vaccine study. You may still be able to take part in our study if this applies to you. In this case, we will contact the team who ran the Hepatitis C vaccine study. We will only do this with your written consent. A copy of this consent will be held by both ourselves and the team responsible for the Hepatitis C vaccine study, they will hold your form in the same way they described when you originally joined the study. We will check your Hepatitis C status with them before enrolling you in this malaria vaccine study.

Vaccination Visits

The table below shows each group and the vaccinations they will receive. Each vaccination will be given together with the Matrix-M adjuvant. The study doctor will talk to you about which group you would be enrolled in.

As this is the first time that RH5.2-VLP will be tested in healthy adults in the UK, enrolment into Group 1 will be staggered. The first participant recruited to Group 1 will be vaccinated and monitored for 48 hours. Following this, two further participants in Group 1 will be vaccinated and monitored for 48 hours. If there are no safety concerns, the remaining 5 participants in Group 1 will be vaccinated. We will only begin recruitment into Groups 3,4 and 5 after all participants in Group 1 have had their second vaccination.

Participants in Groups 1,3,4 and 5 will each receive three vaccinations during the study. Participants in Group 2 will receive three vaccinations and then undergo the malaria challenge, where they will be infected with the malaria parasite to find out how effective the RH5.2-VLP vaccine is preventing disease. Participants enrolled in Group 6 will take part the malaria challenge **only**. There is a separate information sheet about joining Groups 2 and 6.

Group	Vaccine on day 0	Vaccine on day 28	Vaccine on day 56	Vaccine on day 182	Malaria challenge
1	**RH5.2-VLP**	**RH5.2-VLP**	**RH5.2-VLP**	**-**	
2	RH5.2-VLP	RH5.2-VLP	-	RH5.2-VLP	Yes
3	**RH5.2-VLP**	**RH5.2-VLP**	**-**	**RH5.2-VLP**	
4	**RH5.2-VLP**	**RH5.2-VLP**	**-**	**RH5.1**	
5	**RH5.1**	**RH5.1**	**-**	**RH5.1**	
6	-	-	-	-	Yes

Vaccinations will be given into the muscle of the upper arm (alternating for each vaccination).

We will ask you to wait for 60 minutes after each vaccination to check there are no immediate problems. You will be given a thermometer and tape measure to take away. We will also show you how to use the electronic diary. There will also be a paper diary available if you are unable to use the electronic diary. We will ask you to record your symptoms and any redness at the vaccination site every day for 7 days

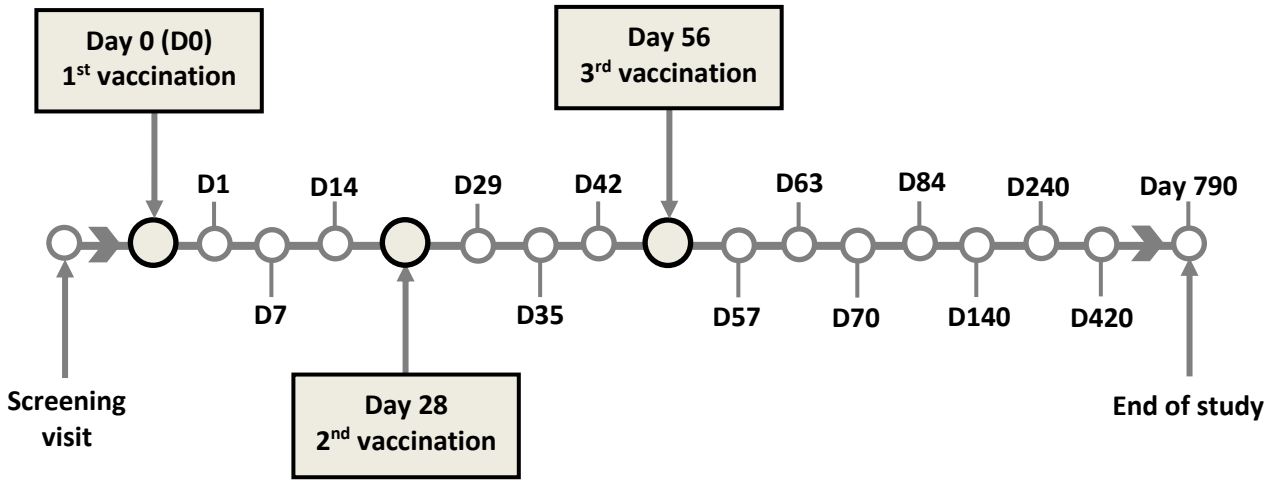
after each vaccination. After the first 7 days, we will ask you to record if you feel unwell or take any medications over the next 3 weeks.

We may ask to photograph your vaccination site. You can choose whether or not to agree to this when you sign the consent form. Your face, and other identifying features (e.g. tattoos/prominent scars), will not appear in these photographs. 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.

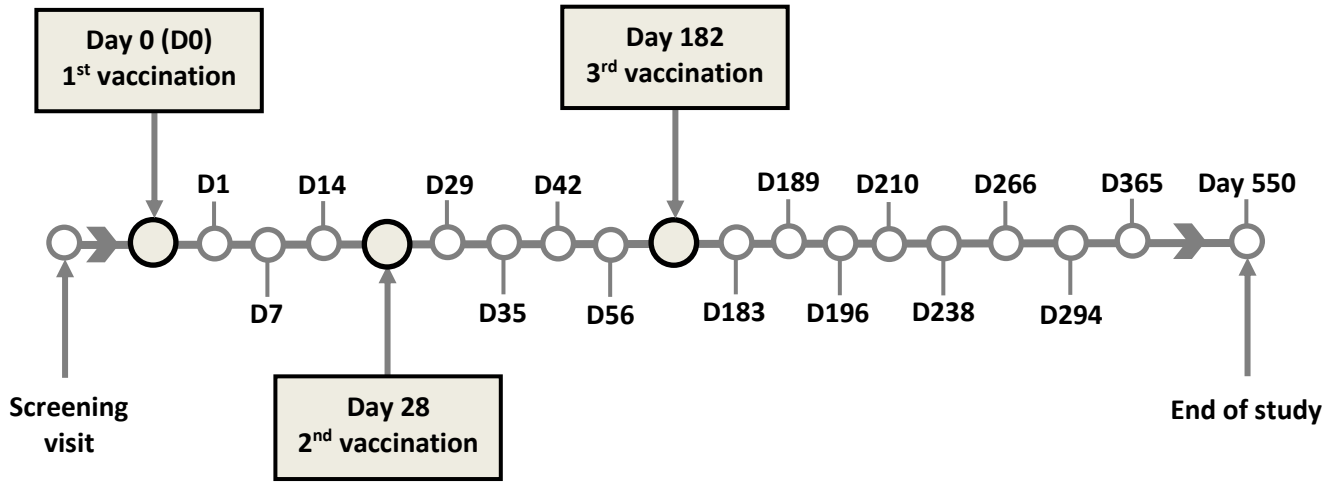
Follow-up visits

The diagram below shows the timing of post vaccination follow-up visits. Visits include a medical assessment and examination by a doctor if needed. We will also take temperature, pulse and blood pressure readings as well as blood tests.

Group 1



Groups (2)*, 3, 4 and 5



*Group 2 will follow this schedule as well if the malaria challenge does not go ahead

Expenses and Payments

You will be compensated for:

- Travel expenses: £30 per visit
- Time required for visit: £40 per hour
- Inconvenience of blood tests: £20 per blood donation

If you choose to leave the study early, or are withdrawn, you will be compensated according to the length of your participation. This will be calculated based on these figures. **Compensation payments received in this trial may have an impact on your entitlement to benefits.**

Group No.	Time in Trial (approx.)	No. of Clinic Visits	Compensation Amount
1	2.5 years	19	£1,790
3-5	1.5 years	20	£1,880

What do I have to do?

- You **must** attend all the visits that are outlined above.
- You **must** complete an electronic diary following vaccination.
- If you are able to become pregnant you **must** use effective contraception until 3 months after your final study vaccination.
- You **must not** donate blood during the study.

What alternatives are present?

Your alternative is not to take part in this study.

PART 3: RISKS AND BENEFITS

What are the risks of taking part?

The potential risks are as follows.

Blood Tests

The total volume of blood taken during the study depends on the group. The amount taken at each visit will vary between around 2mL (less than a teaspoon) to a maximum of 96 mL (about 7 tablespoons). The volume of blood being taken over the course of the trial should not cause any problems in healthy people. There may be some temporary mild discomfort. This may include bruising and tenderness at the site where the blood is taken. You may feel faint as a result of collecting blood.

We will give you a copy of your blood test results if you ask for them. We will only send the results to your GP if you wish us to and will not report them to anyone without your permission.

If abnormal results or undiagnosed conditions are found in the course of the study these will be discussed with you. If you agree, your GP will also be informed. For example, a new diagnosis of anaemia might be made. Any newly diagnosed conditions will be looked after by your GP within the NHS.

At different time points throughout the trial, we will take blood samples for the following tests:

- Your full blood count, liver and kidney function
- Blood borne infections (HIV, hepatitis B & C)
- Thalassaemia and sickle cell anaemia and other conditions that affect the blood
- Genetic analysis of your cells (to look at patterns of genes that can affect the immune system) and the parasites
- Immune responses to vaccination. This may include production of specific antibodies called monoclonal antibodies

Vaccination Side Effects

Once the vaccinations have been given they cannot be undone. It is therefore important you understand the potential risks of the RH5.1 and RH5.2-VLP vaccines before you join the study.

The combination of RH5.2-VLP with Matrix-M has not been used in healthy adults in the UK before. However, we do not expect the side effects of this vaccine to be very different from similar vaccines. This includes RH5.1 with Matrix-M. The most common side effects experienced by volunteers who received RH5.1 with Matrix-M are described below.

We expect that most symptoms will be mild. However, some may be moderate or severe. Symptoms should last no more than a few days. You may experience any of the following side effects:

- Injection site pain. This is most likely to be 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 that 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. There is a small possibility of moderate or severe symptoms occurring.

It is important to remember RH5.2-VLP is being tested in humans for the first time in this trial. This means 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 low risk of serious reactions. These may be related to the nervous system or the immune system.

Severe allergic reactions to vaccines (anaphylaxis) are very rare but can be fatal if not immediately treated. Therefore, we will have doctors qualified in the management of anaphylaxis at each vaccination. Appropriate equipment and medication will also be present.

Reactions in the nervous system are also extremely rare. However, vaccines can cause an illness called Guillain-Barré syndrome. This is an illness in which people can develop severe weakness. It 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 study doctors. Study doctors are available 24 hours a day. We will give you emergency contact details when you attend the vaccination visit.

COVID-19 vaccination

- Please inform us if you have an appointment for COVID-19 vaccination during the trial. We would like to avoid giving you malaria vaccinations around the time of COVID-19 vaccination. This is because it is not known what effect COVID-19 vaccination and malaria vaccination may have on each other.
- You will be able to receive a COVID-19 vaccination if it is given at least 14 days before or 7 days after any malaria trial vaccinations. The malaria vaccinations can be fitted around any COVID-19 vaccination.

There may be other risks, or side effects, which are unknown at this time.

What are the possible benefits of taking part?

This study will not benefit you. The information gained from the trial might help to prevent malaria infection and disease in those who live in areas where malaria is common and in travellers. There are other malaria vaccines in various stages of development.

PART 4: OTHER INFORMATION ABOUT THE STUDY

What if relevant new information becomes available?

Sometimes during the course of a research project, new information becomes available. If this happens, we will tell you about it. We will discuss whether you want to or should continue in the study. If you decide to continue in the study, 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 without your consent for other reasons.

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

You are free to withdraw from the study at any time without giving a reason. This will not result in any penalty, or loss of benefits to which you are otherwise entitled. Your data collected and blood samples taken will continue to be used unless you state otherwise. You may request that your blood samples and research data are destroyed at any time during or after the study, although once the study data is fully anonymised it will not be possible to withdraw this.

Your compensation would be paid as a proportion of the total compensation according to the length of your participation.

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. If necessary, they will refer you to a doctor within the NHS for treatment. 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.

The Investigators recognise the important contribution that volunteers make to medical research. They 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.

Complaints procedure

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). You may also contact the University of Oxford Research Governance, Ethics and Assurance (RGEA) office on 01865 616480 or the head of RGEA, email RGEA.Complaints@admin.ox.ac.uk. The RGEA office can also be contacted if you have questions about your rights as a trial volunteer.

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. Personal details will be stored securely and separately from the research data. Responsible members of the University, independent monitors and the regulatory authorities may be given access to data for monitoring and/or audit of the study. This is 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. 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 to say 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

also check there are no medical reasons that they are aware of that would make your taking part inadvisable. Your GP may be asked to share information about your medical history and give access to any other medical records as needed. The researchers will not enrol you in the trial if your GP has concerns about your eligibility or safety. We will write to your GP to let them know whether or not you are enrolled in the study. We will also write to let them know whether or not you completed the study, so they can update your medical records accordingly.

Prevention of 'Over Volunteering'

Volunteers taking part 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*. Your national insurance or passport number is also required to allow processing of compensation payments.

What will happen to any research samples I give?

All samples will be stored in a pseudo-anonymised form. This means that your study number rather than your personal details will be on them. Your study visit samples 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. Some cells from your blood may be used to produce specific antibodies ('monoclonal antibodies'), which could be used for commercial activity in the future. Other tests to look at the response of your body to the study 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 pseudo-anonymised.

After the study, your leftover samples will be stored indefinitely at the University of Oxford. This will be coded with a study number. Your personal details will also be stored securely and separately from the research data and sample itself until the samples have been depleted or destroyed in order to comply with the Human Tissue Act. The samples may be used for further related research, including of the human body's immune response, vaccine research and/or your safety. Any such future research will have an appropriate ethical review. You may request that remaining samples are destroyed at any time by informing the study team of this decision.

Urine samples will be destroyed immediately after testing.

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, so-called "gene expression". We will not sequence your whole genome. As these tests are not done to look at your health we would not give you these test results.

What will happen to my data?

Data protection regulations require 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, 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 information from you and your medical records in order to undertake this study. We will use the minimum personally-identifiable information possible.

The University of Oxford will keep identifiable information from participants collected during the study initially for 5 years after the study has finished. Once the study has been completed, all documents would be archived in a secure facility. In addition, we will securely store the pseudo-anonymised research data and any research documents with personal information, such as consent forms, initially for 5 years after the end of the study. The need to store this information for longer, in relation to licensing of the study

vaccine will be reviewed every 5 years. Files will be confidentially destroyed when storage is no longer required. For effective vaccines that may be licensed, secure storage of research data may be required for at least 15 years after the end of the study, subject to changes in clinical trials regulations. In addition to the 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. We will also 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 end of the study, unless you consent otherwise, 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 at CCVTM, personal information and medical information including blood test results may be accessed to avoid unnecessary repetition.

Your information may also be shared with partners working with Oxford University. This information will be identified only by the unique trial number. You will not be personally identifiable. All data received will be kept securely by these parties in line with all regulatory requirements. If the study is paused due to safety concerns relating to the study vaccine, the local ethics committee, the study funders (PATH) and the manufacturers of the vaccine adjuvant (Novavax) will be informed. The data shared would be pseudo-anonymised.

Your bank details will be stored for 7 years in line with university financial policy. Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at: https://compliance.web.ox.ac.uk/individual-rights.

Your research records may be reviewed by USAID staff and consultants. You will not be personally identifiable from these records. USAID is providing funding for this research. These persons review records to be sure the research is done in a safe manner that protects you and others.

Involvement of the OVG Quality Assurance Team (Independent Monitors)
The OVG Quality Assurance Team act as independent monitors on behalf of the sponsor to ensure we are complying with the clinical trial regulations. They will conduct a site visit to prepare and set up the clinical trial prior to recruitment as well as conduct monitoring visits to check the information in source documents (e.g. blood test results and GP letters). In most documents you will only be identified by a study ID number but they will see some documents which would identify you (e.g. the consent form). They will not retain any data which could identify you personally. For remote monitoring to occur they may require secure online access to electronic documents but will not download or copy them. The OVG Quality Assurance Team will comply with the University's Information Security Policies, which are documented in the agreement with the University.

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. When we know the results of the study, we will send participants a summary of findings.

The anonymised data from this study will be shared with the partners who are organising and funding this research work. It may be made open to the public so that others can learn from it. If data are shared publicly, they will not be linked to you personally. 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.

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.

A description of this clinical trial will be available on 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. This is so we may inform you of opportunities to take part in future vaccine related research. This is entirely optional. Taking part in this study will not be affected by your decision whether to allow storage of your contact details beyond your participation in this trial.

Your details will be stored electronically on a secure server. 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. 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 by PATH (www.path.org), through a grant from USAID. PATH is an international public health organization. USAID is an international development agency funded by the U.S. government. Neither your GP nor the researchers are paid for recruiting you into this study.

The Senior Laboratory Investigator, Professor Simon Draper, has an interest in patents relating to the RH5-based vaccines and is a shareholder in a company developing vaccines using SpyTag-SpyCatcher technology used in this study. The Chief Investigator, Dr Angela Minassian, has a family member who is an inventor on patents for RH5-based vaccines and a shareholder in a company developing vaccines using SpyTag-SpyCatcher technology. While both Dr Minassian and Professor Draper therefore have a conflict of interest, the integrity of the trial is maintained by samples being analysed by non-clinical researchers who cannot link them to individuals (thereby ensuring no bias), as well as the monitoring of safety by an independent Data Safety Monitoring Committee.

Who has reviewed the study?

This study has been reviewed by the National Research Ethics Service Committee [London- City & East] 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. Information regarding the study has also been reviewed and approved by the Medicines and Healthcare products Regulatory Agency (MHRA).

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
E-mail: info@ovg.ox.ac.uk ; Tel: 01865 611400
CCVTM, Churchill Hospital, Old Road, Headington, Oxford, OX3 7LE