

## VAC071 COVID-19 INFORMATION SHEET AND CONSENT FORM

### Participating in a malaria vaccine and challenge study during the COVID-19 pandemic

Thank you for volunteering to take part in the VAC071 study. Due to the COVID-19 pandemic, some of our study procedures have changed and enhanced precautions will be in place to keep you as safe as possible whilst continuing the study effectively. These changes will follow the latest guidance from Public Health England (PHE) and the UK Government to minimise the risk of transmission of possible COVID-19 infection when you attend clinic appointments. Please read the information below carefully and sign to state that you understand and agree to abide by the changes.

The risks to a person if they contract COVID-19 and malaria around the same time is not known. Therefore we will carry out a COVID-19 swab test before malaria challenge and will not proceed with the challenge if you have a positive COVID-19 test. You may also be directed to local NHS testing if you develop symptoms that could be consistent with COVID-19 infection during the course of the study.

The results of any COVID-19 swab tests done as part of this study must be passed on to Public Health England (including tests that are negative). We will pass your details (name, date of birth, contact details, ethnicity, NHS number) and date of diagnosis and symptom onset if applicable on to Public Health England, as COVID-19 is a 'notifiable disease' and this is a legal requirement.

If you test positive for COVID-19 through this study:

- Please self-isolate as per latest government guidance
- You will be directed to local NHS services if you require further medical care for COVID-19

If you have to self-isolate during the course of the study, we will try to re-schedule clinic visits that are due to another time. However we will sometimes require you to attend clinic whilst you are self-isolating. When you are self-isolating please travel to clinic by means other than public transport, to minimise the potential risk of transmitting the virus to other members of the public.

To minimise the number of people in the building during study visits, we will give you a specific appointment time for all study visits and you must attend then. If you arrive before your appointment time, please wait outside of the building.

#### 1. Clinic visits

- All staff will use appropriate personal protective equipment (PPE) during clinic visits. Social distancing will be strictly observed, unless proximity is required for clinical reasons.
- In the following circumstances, **please do not attend clinic** and call to inform us:
  - o If you or a household member have any symptoms of COVID-19: fever of 37.8°C or higher, new cough, loss or change in sense of smell or taste.
  - o If you or a household member have been diagnosed with COVID-19 and are self-isolating.
  - o If you are unwell or not sure that you should attend.

## **2. Vaccinations**

- Fever can occur within the first few days following vaccinations. If you develop a fever after your vaccination, you will be required to self-isolate. Please let us know so we can discuss arrangements for your post-vaccination visits. You can stop self-isolation once you have been fever free for 24 hours.
- If you continue to have a fever after 48 hours following vaccination, then this is less likely to be due to the vaccination and you will be advised to get tested for COVID-19 through local NHS facilities.

## **3. Malaria Challenge**

- We will carry out a COVID-19 nose and throat swab test two days before malaria challenge. If you test positive for COVID-19, we will not proceed with the malaria challenge.
- Following malaria challenge, you may develop a fever, which could be caused by malaria or another illness, including COVID-19. If you develop a fever after undergoing malaria challenge you must self-isolate and call to inform us. A study doctor will assess how likely it is that you have developed malaria infection, depending on how many days it has been since the malaria challenge and previous blood tests (if applicable).
  - o If it is unlikely that you have developed malaria, we will ask you to continue self-isolating and arrange COVID-19 testing via local NHS facilities. Your remaining follow-ups will be arranged based on the result of the test.
  - o If it is possible that your fever is caused by malaria, we will ask you to attend your follow-up appointment. We will complete the appointment with appropriate precautions to ensure that you do not come into contact with other volunteers. We will collect samples, which may include a nose and throat swab for COVID-19 testing, along with blood for malaria testing. You will then be asked to continue self-isolating until we contact you with further instructions.
- If you test positive for COVID-19 after undergoing malaria challenge we will give you anti-malarial treatment, even if you have not been diagnosed with malaria yet.
- We will carry out a COVID-19 swab test on the day that you are diagnosed with malaria and commenced on malaria treatment. This is because a fever is common around the time of malaria diagnosis and a negative COVID-19 swab means that we can rule out COVID-19 infection and you do not have to self-isolate.

## **4. COVID-19 vaccination**

- Please inform us if you have an appointment for COVID-19 vaccination during the trial as we would like to avoid giving you malaria vaccinations or malaria challenge around the time of COVID-19 vaccination. This is because it is not known what effect COVID-19 vaccinations may have on your response to malaria vaccination and malaria infection, which is being studied in this trial. Similarly it is not known if your response to COVID-19 vaccination may be affected if you are given a malaria vaccine or are infected with malaria around the same time.
- You will be able to receive a COVID-19 vaccine at the following times during the study:
  - o If it is given at least 14 days before or 7 days after any malaria trial vaccinations. We have some flexibility in the dates of your malaria vaccinations so they can be fitted around any COVID-19 vaccination.
  - o If it is given at least 14 days before the day of malaria challenge or after you are diagnosed with malaria and have completed the 3 days of antimalarial treatment. For the majority of participants this will be within 3 weeks after the day of challenge.
  - o If you are offered a COVID-19 vaccine after you have undergone malaria challenge but before completing malaria treatment, we would advise you to delay the COVID-19 vaccine

until after you have been diagnosed with and completed treatment for malaria. If you do not wish to delay your COVID-19 vaccination, you will be given antimalarial treatment at that time point and be withdrawn from the study.

As the public health situation evolves, we may change some of these procedures, in line with the most up-to-date guidance from Public Health England and the UK Government. We will inform you as soon as possible of any changes. If you have any concerns about any of the information in this information sheet, please call or email us. One of the study team will be happy to speak to you.

I \_\_\_\_\_, have read the above information and understand it. I have been given information about the precautions taken during the COVID-19 pandemic and agree to abide by the latest UK Government guidance on self-isolation and testing whilst in the study.

Signature:

Date: