COVHIC003
Participant Information Sheet

Study Title:	**Development of a Controlled Human Infection Model for SARS-CoV-2 Omicron Subvariants (COVHIC003)**
PIS Version and Date:	V2.2 10AUG2026
Sponsor:	Imperial College London
Sponsor Reference:	172082
Chief Investigator:	Professor Christopher Chiu Department of Infectious Disease, Imperial College London
Principal Investigator:	Professor Helen McShane
Study Site:	Oxford

You are being invited 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 will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Study Summary

COVHIC003 is a study that aims to develop a safe "controlled human infection model" (CHIM) study with SARS-CoV-2 (the virus that causes COVID-19) in healthy, vaccinated participants. CHIM studies involve the deliberate infection of a participant with a virus, in a safe and controlled way within an isolation room, in a quarantine facility. By doing studies like this, we can understand more about the infection and why people respond to infection differently. The variant of the SARS-CoV-2 virus used in this study is known as the Omicron EG.5.1 variant.

During this study, you will **deliberately be given the Omicron EG5.1 strain of SARS-CoV-2 and may develop COVID-19.** The study virus is given by drops in the nose (known as inoculation or challenge). Therefore, you might get a COVID-19 infection. You may develop COVID-19 symptoms, such as tiredness, cough, fever and (uncommonly) loss of smell and/or taste. You will be cared for within a hospital setting (quarantine facility) during the potential infection. There is a very small risk that you could become seriously unwell if you develop COVID-19, but this is extremely rare in healthy, vaccinated people.

Prior to receiving the virus, you will undergo Pre-Screening and Screening tests to ensure you are healthy and able to take part in the study. If eligible, you will be admitted to a designated quarantine unit where you will stay in isolation in a single en-suite room. You will check into the quarantine unit 2 days before you are given the virus (known as Day -2) for additional screening tests. You will be given the virus on Day 0.
You may or may not develop COVID-19 after receiving the virus.

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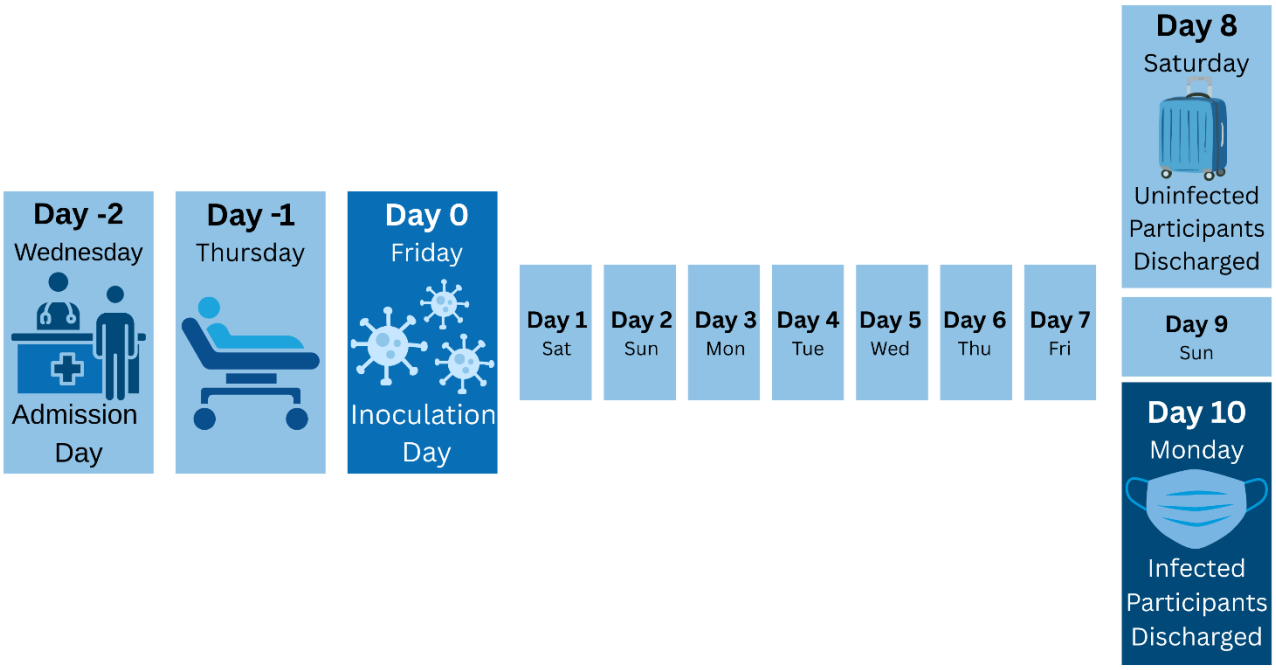
If you remain **uninfected**, you can leave the quarantine unit **eight days later (Day 8)**, but will be required to attend in-person visits on Day 9 and 10. If it is difficult for you to attend these visits from home you may be able to stay in the quarantine unit until Day 10 if agreed in advance with the study team.

If you become **infected**, you will be required to stay in the quarantine unit until **at least Day 10**. If you are still infectious, you may need to stay longer to limit the risk of the virus spreading.



After you are discharged from the quarantine unit, you will be asked to attend for follow up visits on Day 14 (around 14 days after being given the virus), Day 28, Day 90 and Day 180.

You are free to withdraw from the study at any time.

You may be eligible to take part if you:

- ✓ are 18-50 years old
- ✓ are generally healthy
- ✓ have received at least one COVID-19 vaccine
- ✓ can complete the quarantine and follow-up visits

You would not be eligible to take part if you:

- × have significant medical conditions
- × are pregnant
- × live with anyone considered clinically vulnerable
- × have other factors that increase the risks of COVID-19

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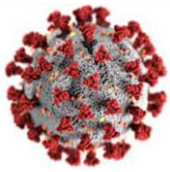
1 What is the purpose of this study?

SARS-CoV-2 continues to change over time, and new variants can still cause infection even in people who have been vaccinated. This study aims to help us understand how the Omicron EG.5.1 variant behaves in healthy vaccinated adults. In this study, researchers will deliberately give participants the virus at a known time and in a controlled setting. This allows us to study infection much more closely than if someone caught the virus naturally.

Up to 38 people will enter this study to find out:

- How much EG.5.1 virus is needed to cause infection in vaccinated people.
- How long vaccinated people are infectious for after "breakthrough" infection.
- What happens in infected people with no symptoms.

1.1 What is SARS-CoV-2 and COVID-19?



SARS-CoV-2 is the virus that causes COVID-19. Although vaccines are available, being vaccinated does not reliably prevent people from transmitting the virus and research is still needed to understand the reasons for this.

1.2 Why are controlled human infection models (CHIM) so important?

CHIM studies involve giving a controlled amount of the virus to individuals at a specific time (rather than people catching it naturally), which means we can get very detailed information about COVID-19 infections.

Reason	Why it matters
To understand why people, respond differently to infection	Helps identify immune responses linked to protection and vaccine effectiveness.
To test new vaccines and treatments faster	Supports quicker development of vaccines that reduce transmission.
To measure when people are infectious	Improves understanding of how long people can spread the virus, even before they have symptoms.
To study infection in people with no symptoms (asymptomatic)	Helps develop between ways to reduce silent transmission.

2 Why have I been given this participant information sheet?

You have been given this information sheet because you expressed an interest in the study. Before participating in this study, we need to make sure that you fully understand why the study is being done, what the possible risks are, and what taking part would involve.

Please make sure you read and understand this document before you make the decision to take part. If you have any questions or concerns, please ask a member of the study staff and, if you want to, discuss any of this information with your family, friends, and your General Practitioner (GP).

3 Do I have to take part?

No, taking part in research is entirely voluntary. It is up to you to decide whether to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. You are still free to withdraw at any time and without giving a reason. A decision to withdraw, or

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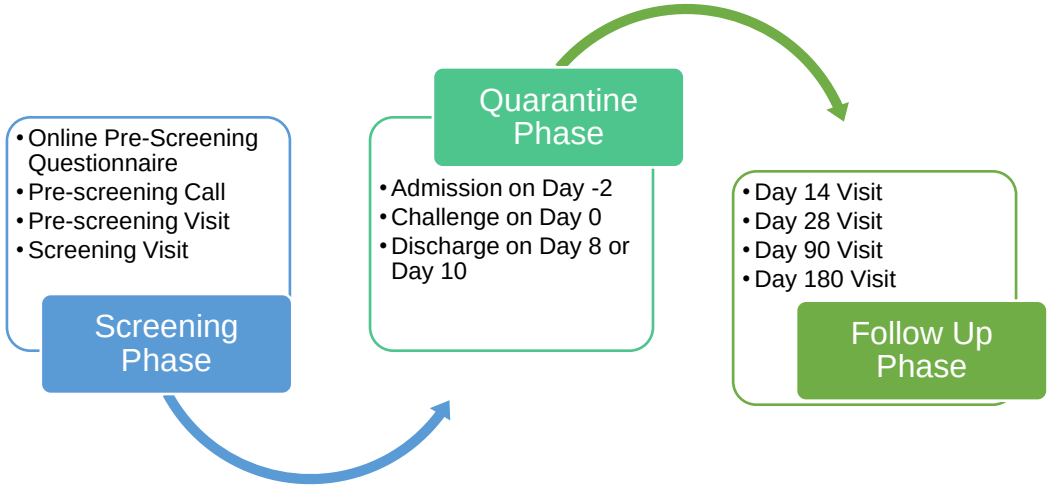
a decision not to take part, will not affect the standard of care you receive now or in the future. You will be paid for the time you have spent in the study (see Section 4.8).

3.1 What should I do if I want to take part?

If you haven't already, register your interest by visiting https://www.jenner.ac.uk/volunteer/recruiting-trials to complete the online pre-screening questionnaire, or contact the study team at Covid19-challenge@paediatrics.ox.ac.uk. The study team will then get in touch to explain the study, answer your questions, and check your eligibility. If suitable, you may be invited for a pre-screening visit (see Section 4.1).

4 What does the study involve?

The study is split into screening, quarantine and follow up phases and activities may vary between study sites.



Study Site	Screening Phase	Quarantine Phase	Follow-up Phase
Imperial Clinical Research Facility, Hammersmith Hospital, London	☑	☒	☑
Royal Free Hospital, London	☒	☑	☒
Guy's and St Thomas' Hospital, London	☑	☒	☒
University of Oxford	☑	☑	☑
Southampton Clinical Research Facility, , Southampton	☑	☒	☑
Liverpool School of Tropical Medicine, Liverpool	☑	☑	☑

4.1 Pre-Screening

Complete the **online pre-screening questionnaire** to see if you might be eligible to take part.

- ☒ If your answers indicate that you are not eligible, the questionnaire will inform you of this and will not collect further information from you.
- ☑ If your answers indicate that you might be eligible, you will be asked to provide your details for the study team to contact you.

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A member of the study team will then contact you by phone to ask further questions pertaining to the full study inclusion/exclusion criteria.

- ☒ If you do not appear to meet the criteria, the study team will let you know and thank you for your interest.
- ☑ If you provisionally meet the criteria based on your answers, the study team will invite you for a pre-screening visit.

During the pre-screening call, the study team will discuss the pre-screening process with you and answer any questions. At the pre-screening visit, you will:

Be asked to sign the Pre-screening Informed Consent Form

Have height and weight measurements to calculate BMI

Provide your contact details and demographic information

Have your pulse rate, breathing rate, blood pressure, temperature and oxygen saturation checked (Vital Signs)

Provide information about your medical and medication history

Provide a blood sample for SARS-CoV-2 antibodies

Provide information on your COVID-19 vaccination history and any prior COVID-19 infections

Optional: Have a nasosorption (SAM) sample for SARS-CoV-2 antibodies

We collect a blood sample for SARS-CoV-2 antibodies as we are looking to enrol participants who have low antibody levels. This is because we know it is very unlikely that people with high antibody levels will become infected.

Only around 20% of participants who come for pre-screening will have low enough antibody levels to move to the next phase.

- ☒ If your antibody levels are too high, the study team will contact you to explain the antibody test results.
- ☑ If your antibody levels are lower than our threshold, you will then be invited for a full screening visit.

You will be paid £40 for attending this initial pre-screening visit regardless of whether your antibodies meet our criteria or not.

4.2 Screening

The screening visit can happen up to 90 days (3 months) prior to the quarantine phase. At the visit, the study team will discuss the whole study with you and answer any questions. If all your questions have been answered and you would like to go ahead, the study doctor will ask you to read, sign and date the relevant consent form. They will then also sign this consent form and provide you with a copy.

After this, the study team will carry out the following:

Full medical and medication history.

Pulse rate, breathing rate, blood pressure, temperature and oxygen saturation checked (Vital Signs).

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Questions about current weekly alcohol and/or smoking consumption.

Mental health questionnaires.

MRC Dyspnoea (Breathlessness) Scale.

If your MRC Dyspnoea score indicates further testing, a lung function test (spirometry) may be performed at either the screening visit or at baseline (admission to quarantine).

Examination for signs of illness or disease (a physical examination).

Electrocardiogram (ECG).

Urine samples to test for drugs of abuse & pregnancy in people of child-bearing potential.

Blood samples obtained for:

- Safety blood tests, including full blood count, renal and liver function tests.
- Hepatitis B and C, and HIV (the virus that causes AIDS).
- Human leukocyte antigen (HLA) typing (a genetic test).

Nose and throat samples.

Chest X-Ray.

British citizens must provide proof of their National Insurance (NI) number, or a passport if they do not have one, so the study team can register them on The Over-Volunteering Prevention System (TOPS). TOPS helps prevent participation in multiple clinical trials too frequently for participant safety.

We will also need to review your medical history records. Sometimes, the study team can review a summary care record for you on the hospital's electronic patient records system (called Cerner). The study team will not look at this until you have signed the informed consent form.

If your GP practice uses ACCURX, the study team may request access to your medical summary using a code sent to your phone, which you will share with the study team for review during your visit.

If we cannot find your medical records on these systems, the study team will send a letter and copy of your consent form to your GP requesting a summary your medical and medication history.

After the screening visit, once all the test results and, if applicable, the GP summary has been reviewed, the study team can determine your eligibility. You can still change your mind at any time and withdraw from further assessments and study participation.

- ☒ If you are not eligible, because the test results have identified something that makes you ineligible for the study, the study team will discuss this with you. If any abnormal results are found and we feel need further action, we may inform your GP or another healthcare professional, so they can arrange to follow up with you.
- ▪ After screening, some participants may be "temporarily ineligible" but can enter a quarantine later in the study. The study team will explain this to you if you may be eligible later on and if any repeat assessments are required.
- ☑ If, based on the screening results, you are eligible for the study, you will be contacted to discuss upcoming quarantine dates and locations.

You will be paid £125 for your time for attending a screening visit regardless of whether you are deemed eligible for the study or not.

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If your Hepatitis B test comes back positive, it is compulsory for your diagnosis and personal details to be reported to public health authorities. If your HIV test comes back positive, this will be reported confidentially to the national surveillance system.

4.3 Quarantine Phase

Quarantines take place at the following locations:

Oxford: Experimental Medicine Clinical Research Facility (EMCRF), University of Oxford

Royal Free Hospital: Royal Free London NHS Foundation Trust, London

Liverpool Human Challenge Facility: Liverpool School of Tropical Medicine, Liverpool

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The study teams at all the sites liaise very closely with each other, and we will do our best to accommodate you at your preferred quarantine site where possible.

At the quarantine unit, you will be provided with:

- A single room with en-suite bathroom
- Breakfast, lunch, dinner and snacks delivered to your room
    - catering for vegetarian, vegan, halal, kosher and gluten free
- Fresh bedding, linen and towels
- WiFi
- Fridge

In Oxford, you will have a kettle to make your own hot drinks. There is no TV in the Oxford rooms, so participants are encouraged to bring a personal device to use streaming services.

In Royal Free, there is no kettle, but the study team can bring hot drinks at your request. They do have a TV in the room.

In Liverpool, you will have a kettle to make your own hot drinks. There is a TV with access to streaming services in the room with an HDMI port near the bed to use personal devices or games consoles that you may wish to bring to the facility.

There are no laundry facilities at the quarantine units so you will need to pack enough clean clothes for the duration of your stay.

4.4 Transfers

Some study sites do not have quarantine units, so you may need to transfer to another site for the quarantine phase. Any transfer will be discussed with you in advance, and your details and study

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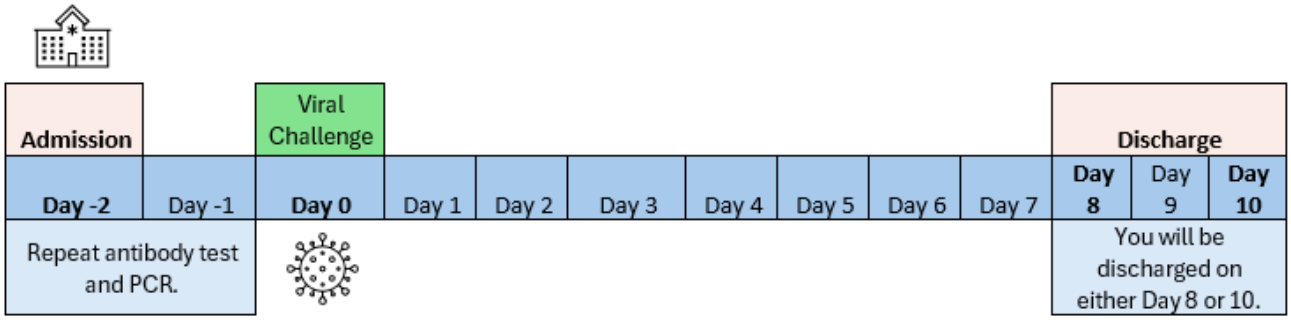
records will only be shared securely with your agreement. The new site will provide its local participant information sheet, explain any differences, and ask you to re-consent at your first visit.
If you are asked to travel to a quarantine site which is not at the site you undertook the screening phase of the study, your travel expenses will be reimbursed – see Appendix 2.

4.5 Pre-admission

Before admission, the quarantine team will contact you to discuss the quarantine process and confirm any changes to your health, medications, or availability. They will also review dietary requirements, what to bring, daily routines, exercise, and any medications or supplements that may need to be stopped before quarantine.

Please avoid excessive alcohol for 72 hours before admission, avoid strenuous exercise for 48 hours before admission, and note that alcohol is not permitted during quarantine. Smoking, illegal drugs, and legal highs are strictly prohibited before and during the quarantine period.

4.6 Admission (Day -2)



You will check into the quarantine unit two days before you are given the virus.

The study team will do some more tests to review your eligibility to take part once more. These tests will include ECG, blood tests, vital signs, a physical examination and urine tests (including urine screening for drug misuse). People of child-bearing potential will have a blood test to check there is no evidence of pregnancy. Mental health assessment questionnaires may be performed at the study team's discretion to assess your well-being.

The study team will repeat your COVID-19 antibodies and collect a respiratory PCR via a nasal swab.

- ☒ If your antibodies have increased to above the threshold, or if you are found to have a respiratory virus (from the PCR test), you will be discharged and unable to proceed with the viral challenge.
- ☒ If we identify any abnormalities, we may cancel ***or postpone*** your quarantine stay.
- ☑ If you are well, your antibody levels remain below the threshold, and you have no other respiratory viruses, you will proceed to Day 0 to be challenged with the study virus.

4.7 Reserve Participants

You may be invited as a reserve participant for the quarantine part of the study. If you agree:

- You will be admitted on **Day –2** with other participants and stay in the quarantine unit.
- You will follow the same procedures on **Day –2 and Day –1**.
- If a main participant becomes ineligible, you will continue in the study, receive the virus on **Day 0**, and remain for **8–10 more days**.

If no one drops out, you will be discharged on or before Day 0 and invited for the next quarantine group as a main participant, if you continue to meet the criteria.

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4.8 Challenge (Day 0)

On Day 0, you will receive the SARS-CoV-2 virus as drops placed into your nose. You will be monitored afterwards, although side effects are unlikely.

After receiving the virus, you will be treated as potentially infectious and staff will wear protective equipment when entering your room.

The team will monitor whether you become infected but will not usually share this until near the end of quarantine. Not all participants will become infected.

4.9 During Quarantine

From admission until you are discharged, you will remain in your own en-suite room and should not leave this room. You cannot have any visitors so the only face-to-face contact will be with the study team.

While you are in quarantine, you will have daily blood tests, nasal swabs and other procedures, mainly in the morning with some in the afternoon. You will complete a symptom diary three times a day and have your vital signs checked four times daily. All study assessments will take place during the day, and you will not be disturbed overnight.

The procedures that will be done during quarantine are detailed in Appendix 1.

Please provide accurate medical information, follow study instructions, attend all appointments, and treat staff and participants respectfully.

Additional restrictions on medications, supplements, exercise, and egg donation will be discussed with you by the study team.

4.10 Discharge from Quarantine

If you do not become **infected**, you can leave the quarantine unit on Day 8 and return for outpatient visits on Days 9 and 10. Alternatively, you may be able to stay in the quarantine unit until Day 10 if this is agreed in advance with the study team. If you remain in the unit, you must stay in your room throughout this period. We will tell you your infection status on Day 7. You may also be able to complete the Day 9 and Day 10 visits at your original screening site, if this is arranged before admission.

If you become **infected**, you may still “shed” virus even if you have no symptoms. For this reason, you will need to stay in your room for a minimum 10 days after being given the virus. You may be asked to stay longer if you are still contagious, or the study doctor thinks it is necessary.

Some people remain PCR positive for longer despite no longer being contagious. If you are PCR positive at discharge, you may be asked to complete further PCR swabs at home on Day 21, 28 and then weekly until you have a negative result. If PCR results suggest higher-than-expected levels of virus, you may be asked to take a lateral flow test. You will only need to isolate if the lateral flow test is positive.

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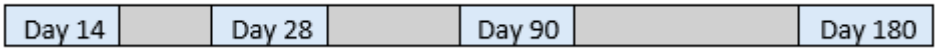
After discharge, you will be provided with contact card with a 24-hour phone number and email address for the study team. At your follow up visits, you can inform the study team if you:

- Develop any new COVID-19 (cold or flu-like) symptoms.
- Have a positive test for COVID-19.
- Receive a COVID-19 vaccine.
- Receive any medical care outside of the study e.g. with your GP or at a hospital.

4.11 Follow-Up

Following discharge from the quarantine unit, you will be asked to attend in-person follow-up visits at the Centre for Clinical Vaccinology and Tropical Medicine. In some cases, it may be possible to attend follow-up visits at the quarantine site or another study site if this is more convenient, but this must be agreed with the study team and may not always be possible.

Please note that travel expenses for follow-up visits cannot be reimbursed.



The follow-ups will take place on Day 14 (two weeks after receiving the virus), Day 28 (1 month after), Day 90 (3 months after) and Day 180 (6 months after). The follow-up visits will include blood samples, nose and/or throat swabs, vital signs, physical exam and other assessments and procedures as detailed in Section 4.6 and Appendix 1. We ask participants to avoid consuming excessive amounts of alcohol 72 hours prior and avoid strenuous exercise 48 hours prior to follow up visits.

Follow-up visits are scheduled on weekdays (Monday–Thursday) between 8am and 11am. Visits outside of these hours can only be accommodated by prior agreement with the study team.

4.12 COVID-19 infection after discharge

Following discharge from the quarantine unit, you will be given lateral flow tests to take home with you. If you develop any symptoms of COVID-19, you will need to take a lateral flow test and contact the study team on the phone number provided so they can collect information on symptoms, concomitant medications, and lateral flow results. The study team may send you a further swab for a PCR test which will have a shipment box for you to return to the laboratory.

4.13 What tests and procedures will I have during the study?

During the study, we will look after you at all times and monitor your health as necessary. If the doctor wants to confirm a test result, they may ask you to have an extra test.

Measurements/Scans	
Vital Signs	We will measure your heart rate, breathing rate, blood pressure, oxygen saturation and temperature.
Physical Examination	A study doctor will perform a general check, including examining your skin, chest, abdomen, mouth, and lymph nodes.
Chest X-Ray	This is performed once at the screening visit and is a safe and painless test that uses a small amount of ionising radiation to take a picture of your chest and lungs.
Electro-cardiogram (ECG)	This looks at your heart's electrical activity. It is a painless procedure where small pads will be stuck to your arms, legs and chest while you lie still for a few minutes.
Spirometry	*Note: This will only be performed at screening or admission to quarantine if you indicate that you experience a certain level of breathlessness at rest or during activity.* Spirometry is a type of lung function test which involves you taking a deep breath into a mouthpiece.
Samples	

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Urine test	You will be asked to provide a urine sample to test for infection, ill health, drugs of abuse, and pregnancy (for people of child-bearing potential only).
Nasal sampling	Nasal swabs will be taken by gently inserting a swab into the front, middle, or back of your nose. Nasal fluid samples will be collected using a soft absorbent strip placed inside your nostril for 2 minutes. These procedures are not painful and do not require anaesthetic, but they may cause brief discomfort, sneezing, watery eyes, a runny nose, or a small nosebleed. The study team will monitor for irritation and use alternate nostrils for sampling.
Throat swabs	Throat swabs are collected from the back of your throat, and a tongue depressor may be used. You will need to resist gagging and closing your mouth.
Lateral Flow Tests	You will be provided with a lateral flow antigen test and asked to the test yourself following the manufacturer's instructions. Once performed, the lateral flow test will be immediately removed by study staff so you cannot read the result.
Blood Samples	We will take blood to test for: • Anaemia (low red blood cells) or problems with your immune system • Blood clotting problems • Liver, kidney, thyroid and heart function • HIV, Hepatitis B and Hepatitis C infection • Diabetes or impaired blood sugar control • Pregnancy • HLA type (this is genetic test which tells us the types of proteins or "markers" on your cells) • SARS-CoV-2 antibodies (to check for evidence of infection and vaccination). We will also collect blood samples for our research.
Environment Sampling	During quarantine, we will collect samples from the air and surfaces.
Mask-wearing samples	You will be asked to wear a single use face mask for 60mins once or twice a day to study the levels of the virus that are present in your breath.

Table 1. Measurements and Samples

4.14 What happens if something unexpected turns up during my tests?

If we find any health abnormalities during the study, we will inform you and, if necessary and, we may inform your GP or other healthcare professionals to take further action.

4.15 What if new information becomes available?

Sometimes during a research project, new information becomes available about the virus that is being studied. If new information arises about the omicron EG.5.1 variant being used in the study, your research doctor will tell you about it and discuss your ongoing participation in the study. If you decide to withdraw, your research doctor will make arrangements for your care to continue. If you decide to continue in the study, you will be asked to sign an updated consent form.
We do not anticipate there being any relevant new information arising for the challenge agent being used in the study.

4.16 Will any genetic tests be done?

We will do genetic tests on your blood samples to look at the patterns of genes that regulate your own individual immune response (these are called Human Leukocyte Antigen HLA genes). Doing this helps us to work out which aspects of the immune response to infection are due to genetic differences between individuals. We may also try to identify and study the genes that appear to be important in response to challenge. These samples will be labelled only with the participant ID number, not your name or contact details. The laboratories analysing your samples will not know your identity.

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Because genetic information is unique to each person, it cannot be completely anonymous, although the risk of identification is very low. We minimise this risk by keeping the Participant ID key securely at the study site, limiting access to authorised members of the study team only, and ensuring that any information shared with research partners is pseudonymised or summarised. No identifiable genetic information is shared outside the UK or with any collaborators, including MUSICC partners.

You should not take part in this study if you do not want genetic testing of your samples.

4.17 What payments will I receive for being in the study?

You will be paid for your participation in the study as follows:

Visit	Amount
Pre-Screening Visit	£40
Screening Visit	£125
Quarantine Stay	£3,370
Extra Quarantine Days (if applicable)	£200 per day
Day 14 Visit	£100
Day 28 Visit	£100
Day 90 Visit	£100
Day 180 Visit	£100
TOTAL	**£3,935**

Table 2. Participant Payment breakdown by visit

Please note, participants who remain uninfected and are discharged from the quarantine unit on Day 8 and who return for the Day 9, and 10 visits will be paid the same total as the infected participants who stay in quarantine until Day 10.

More details on payments can be found in Appendix 2.

4.18 What are the health benefits of taking part?

Taking part will not improve your health, although you may benefit from a general health check.

5 What are the risks of taking part?

5.1 What are the risks from the study virus (SARS-CoV-2)?

SARS-CoV-2, the virus that causes COVID-19, can cause illness ranging from no symptoms or mild cold-like symptoms to more severe disease, although severe illness is now rare in healthy vaccinated adults. Existing COVID-19 vaccines remain highly effective at preventing severe disease, including from the Omicron EG.5.1 variant used in this study. Since 2021, several SARS-CoV-2 controlled human infection studies have been conducted in healthy adults, including vaccinated participants, and no serious safety concerns have been identified. Most infections in these studies were mild and resolved fully, although some participants experienced temporary changes in smell or taste. While no study can eliminate all risks, these previous studies and our current understanding of COVID-19 help us to predict and closely monitor the expected risks in this study. The Omicron EG.5.1 virus used in this study was originally obtained from a person with mild COVID-19 and prepared under highly controlled laboratory conditions to ensure it is free from contaminants.

Risk	Further Information	Mitigation
Feeling unwell due to COVID-19 infection	If you become infected, you may experience the following symptoms: stuffy or runny nose, sneezing, sore throat, headache, tiredness, muscle/joint aches, cough or fever.	We are only enrolling healthy, vaccinated participants at low risk of getting very unwell. The study team will be closely monitoring you every day and can

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Risk	Further Information	Mitigation
	Some people have no symptoms of infection despite being infected.	provide medications such as paracetamol to ease symptoms.
Reduced sense of smell (anosmia)	Most people recover quickly, but some may experience changes to their sense of smell and/or taste for **weeks or months**. Anosmia is less common in individuals infected with omicron EG.5.1 compared with strains earlier in the pandemic, where it was shown that 96% of COVID-related smell problems resolved within a year.	Vaccination significantly reduces the risk of altered sense of smell following infection. Referrals to specialists will be arranged should your smell or taste be altered for a prolonged period. If your work depends on an unaffected sense of smell, participation is **not recommended**.
Long COVID	Some individuals may develop long-lasting symptoms that can persist for months after infection. These may include fatigue, breathlessness, brain fog, joint pain and muscle pains Individuals who are older, female, in poor general health, and with more symptomatic COVID-19 disease are at higher risk of long COVID.	Vaccination significantly reduces the risk of long COVID by up to 50%. In vaccinated individuals with mild infections, the long COVID risk in those under 50 is estimated to be 2-3%. Referrals to specialists will be arranged should you experience any prolonged symptoms consistent with long COVID.
Severe COVID-19 disease	In young adults, severe disease due to COVID-19 is very uncommon, and this risk is reduced even further (up to 80%) by vaccination. The estimated risks following infection in those aged 18-50 who have had a full vaccination course are as follows: • Risk of hospitalisation: less than **1 in 2000** infections • Risk of ICU admission: **1 in 10,000 – 100,000 infections** • Risk of death: less than **1 in 100,000 infections** Other serious risks are listed below. These are extremely rare in young, vaccinated adults • Shortness of breath and low oxygen levels. • Pneumonia (lung infection). • Low blood pressure or shock. • Blood clots – these can develop in the lungs (pulmonary embolism) or legs (deep vein thrombosis) and can rarely lead to strokes. • Kidney damage – this normally resolves with appropriate treatment, but permanent damage may require dialysis or kidney transplant. • Liver damage – this normally resolves with appropriate treatment, but permanent damage may require a liver transplant. • Permanent disability and death.	Our comprehensive screening process ensures that study participants are healthy and do not have any underlying health conditions which put them at higher risk of becoming severely unwell. We will monitor all study participants closely during the quarantine period. If there are any indications that you might be becoming more unwell, we will assess you, give you immediate treatment, and may move you from the quarantine unit into a clinical hospital ward. You would receive the most appropriate treatment according to your needs, such as oxygen, steroids (that reduce inflammation in the lungs), antiviral medicines, ventilatory support or intensive care.
'Rescue therapy' – **Paxlovid (nirmatrelvir/ ritonavir)**	A 'rescue therapy' may be offered to you if you develop certain symptoms (such as a persistent high fever). Paxlovid is an antiviral drug that stops SARS-CoV-2 from multiplying. It is developed by Pfizer and has been given conditional approval by the Medicines and Healthcare products Regulatory Agency (MHRA) for treating patients at risk of progression to more severe illness.	It is taken as an oral tablet for 5 days, so any side effects should resolve after the medication is stopped. You will be closely monitored by the clinical team at the time you are given the drug. Serious allergic reactions may occur but are rare. Treatment for severe

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Risk	Further Information	Mitigation
	Common side effects (up to 1 in 10 people): • Diarrhoea • Vomiting • Altered sense of taste Allergic reactions could happen. Some signs of allergic reaction include • Rash • Difficulty breathing • Swelling around the mouth/throat/eyes • Sudden change in blood pressure • Sweating	allergic reactions will be immediately available if required. Paxlovid can also reduce the effectiveness of some combined oral contraceptive pills, so you will need to use an additional method of contraception during treatment and for 30 days after.
Transmitting the virus to others	When an individual with COVID-19 coughs, sneezes, speaks, or breathes, they produce respiratory droplets carrying the virus. Another person can contract the virus if they inhale these droplets or if the droplets come into direct contact with their eyes, nose or mouth.	Participants in the study are required to stay in quarantine until they are no longer contagious. To minimise the spread of infection, during the quarantine, you must remain in your own room, are not allowed any visitors, and are not allowed to send any materials out, such as mail or packages. Study staff entering your room will be wearing personal protective equipment.
To an unborn child	Contracting COVID-19 can affect both the pregnancy and an unborn child, especially if the infection is severe or occurs during later stages of pregnancy.	You cannot participate in the study if you are pregnant or planning to become pregnant during the study. You must use an effective method of contraception from the date of viral challenge to 6 months after. Acceptable methods of contraception include • The coil • Oral, injected or implanted hormonal contraception • Barrier methods such as condoms • True abstinence from heterosexual sex • Permanent methods such as female sterilisation or vasectomy.
From ionising radiation (X-ray)	As part of the screening process, you will have a chest X-ray to look for any existing lung disease. This procedure exposes you to ionising radiation that you would not otherwise be exposed to. This procedure uses ionising radiation to form images of your body and/or provide treatment and/or provide your doctor with other clinical information. Ionising radiation may cause cancer many years or decades after the exposure. We are all at risk of developing cancer during our lifetime. 50% of the population is likely to develop one of the many forms of cancer at some stage during our lifetime. Taking part in this study will add only a very small chance of this happening to you.	The chest X-ray will be reported by an NHS Consultant Radiologist and any abnormal findings will be appropriately followed up.

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Risk	Further Information	Mitigation
From sample collection	Drawing blood may cause slight pain and occasional bruising where the needle enters. It can cause infection, nerve pain, excess bleeding, clotting, anaemia or some people may feel light-headed or faint. Nose and/or throat swabs may be uncomfortable. Swabbing the back of the throat can cause individuals to cough or gag. Deep nasal swabs (and nasosorption tests) can make your eyes water or cause nose bleeding in rare instances.	We will limit the amount of blood taken to 550ml in any 8-week period, which is a safe amount for healthy participants to give. You should not donate blood from the screening visit to the last 6-month follow-up visit or participate in any other studies where you give blood. We will not enrol you if your blood counts are significantly low at screening (anaemia) and will monitor you for this throughout the study. Nose and/or throat swabs are a safe way of looking for COVID-19 infection and these will be limited to timepoints set out in the schedule of events.

5.2 Are there any other risks of being in the study?

- You may become anxious, lonely or depressed during quarantine and having limited personal private space.
- We are committed to safeguarding your mental health and if we become significantly concerned about your mental health status, we may consider stopping your participation in the study early in your best interests. If needed, we may refer you for specialist mental health assessment and treatment or for follow up with your GP or other healthcare professional.
- Some of the tests or procedures in the study may be stressful or make you worried about how others might see you, such as concern about being tested for HIV.
- If you have any insurance policies, you should check whether taking part in this research study affects them.
- If you receive state benefits you should check if the compensation received from taking part in this study affects any state benefit payments to which you are entitled.
- You should carefully consider the risks involved in taking part in clinical research in the context of your career choices, as long-lasting symptoms may affect your work.

6 What happens when the research study stops?

Your time in the study will end once you have completed your final follow-up visit at 6 months post viral challenge. You will not need to do anything further.

If you require any extra follow up with the study team after your 6-month visit for the purpose of the study, this will be discussed with you. If you require any extra follow up with your GP or other healthcare professional, we will write to them so they can arrange a follow up with you.

6.1 Could my participation end early?

Yes, your participation in the study could end early. At no point can we guarantee that you will complete the study.

The Sponsor (Imperial College London) or the regulatory authorities can stop the study at any time. Additionally, the study doctors could decide to take you out of the study at any point if they think it is necessary, as outlined below.

If you do not cooperate, or, in our reasonable opinion, comply with the study procedures, you may be taken out of the study by the study team, which could lessen the amount of payment you receive.

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6.2 What if I want to withdraw from the study?

6.2.0 Withdrawal during quarantine

You are free to withdraw from the study at any time. However, if you decide to withdraw during the quarantine phase, you will be strongly encouraged to remain in the quarantine unit until you are no longer infectious to reduce the risk of spreading the virus.

- If you withdraw, all research procedures will stop. With your agreement, the study team may continue safety related care, including monitoring your symptoms, vital signs, safety blood tests and any available rescue therapy.

If you decide to leave the quarantine unit early, you will be advised to:

- Self-isolate at home until you are no longer infectious (around 10 days after you were given the virus)
- Follow infection-control guidance such as regular hand-washing
- Travel home by private transport where possible
- Avoid contact with others in your household

6.2.1 Withdrawal at any other time

You are free to withdraw from the study at any time. If you withdraw from the study, we will keep and use information about you that we already have because some research using your data may have already taken place and this cannot be undone. You will be asked how you would like us to use your study samples and information. You may request the destruction of any biological samples collected and not yet analysed. You may also ask the study team to remove your personal details (e.g., address and date of birth) from its participant database. However please note, that any of your data which has been recorded would not be withdrawn or erased from the study so that we can still meet our legal obligations and to maintain the scientific integrity of the study. A record of your decision would be kept.

If you lose the capacity to give informed consent during the study, you would be withdrawn from further study procedures. Any identifiable data or samples that have already been collected up to that point would be kept and used for the research. We may also continue to use your identifiable data or samples that were collected before you lost capacity, but no new data or samples would be collected after this point.

7 What if something goes wrong?

You must tell the study staff immediately if you have any health problems during the study. You will be given an emergency contact card when you are discharged from quarantine, which provides a 24-hour telephone service in case you need to contact us outside office hours. If you need to attend another doctor for health problems relating to the study, we will ask that doctor to provide details that will help us follow up your care and investigate the possible reasons for these health problems.

Imperial College London holds insurance policies that apply to this study. If you experience harm or injury as a result of taking part in this study, you will be eligible to claim compensation without having to prove that Imperial College London is at fault. This does not affect your legal rights to seek compensation.

If you are harmed due to someone's negligence, you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the investigator, Professor Chris Chiu (c.chiu@imperial.ac.uk). The normal National Health Service mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Imperial College Research Governance and Integrity Team (https://www.imperial.ac.uk/research-and-innovation/research-office/research-governance-and-integrity/).

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8 Storage and use of samples and data from this study

Your samples and data will be labelled with a unique participant ID number and will not include your name or other identifiers. This means your samples are pseudonymised, so individuals analysing the samples will not be able to identify you. Only authorised members of the study team at the study site will be able to link this ID number back to you.

The Sponsor and/or the COVHIC003 study sites will keep all the biological samples and related data collected from you during the study to allow us to fully study and understand the disease.

Some samples analysed through NHS hospital systems may be linked to your hospital record, but samples will never include both your personal details and participant ID together.
Your samples will be kept until the end of the study. Any remaining samples will be destroyed at the end of the study unless you consent to future use.

All personal information collected about you during this study will be handled in strict confidence and in accordance with the UK General Data Protection Regulation (UK GDPR) and the Data Protection Act 2018. Your identifiable information (such as your name, contact details, and NHS number) will be stored securely and will only be accessible to authorised members of the study team, the Sponsor (Imperial College London). Your data will be stored in secure systems that meet recognised UK security standards, and appropriate technical and organisational measures will be in place to protect your information from unauthorised access, loss, or misuse.

Any physical documents containing your personal information will be stored securely. Your personal data will also be held securely on a database, treated in strictest confidence and will be held in accordance with data protection legislation. Access to personal information will be limited to authorised staff within Imperial College London, the University of Oxford and other COVHIC003 study sites should you be transferred to them. These organisations have a duty of confidentiality to you as a potential research participant.
Your records and personal information will be treated in the strictest confidence.

Some of your samples and research data will be shared with MUSICC project research partners based in the UK, USA, Australia, Singapore, Belgium, the Netherlands and France. Any data or samples shared will be pseudonymised with your unique participant ID number. Only the minimum necessary data and/or samples required for the research will be shared. All MUSICC partners are required to follow strict data protection and confidentiality agreements. Where data is transferred outside the UK, this will be done in accordance with UK data protection laws using appropriate safeguards, such as Standard Contractual Clauses or UK International Data Transfer Agreements. Sharing of your pseudonymised data and samples with MUSICC partners is a necessary part of this study.

9 Keeping your data safe

9.1 How will we use information about you?

Research Study Title: COVHIC003
IRAS ID: 362560

Imperial College London is the sponsor for this study and will act as the data controller for this study. Being a data controller means that we are responsible for looking after your information and using it appropriately plus are responsible for explaining this to you. Imperial College London will keep your personal data for:

- 10 years after the study has finished in relation to data subject consent forms.
- 10 years after the study has completed in relation to primary research data.

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The study data will then be fully anonymised and securely archived or destroyed.

This study is expected to finish in September 2029.

For more information / confirmation regarding the end date, please contact the study team; see '**Where can you find out more about your information is used**' for contact information.

We will need to use information from you, your medical records and your GP for this research project. This information will include your name, date of birth, NHS number, contact details (phone, email, address), demographic information (age, sex/gender and ethnicity/race) and medical history. We will also collect your passport number or National Insurance number in order to register you on The Over-Volunteering Protection System (TOPS). You can find out more about TOPS here: https://www.hra.nhs.uk/about-us/committees-and-services/the-over-volunteering-prevention-system/. We will also collect your bank details so that we may pay you for your participation in the study.

People within the college and study team (see section 9.3 Sharing your information with others) will use this information to do the research or to check your records to make sure that research is being done properly. and the information held (such as contact details) is accurate.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

Imperial College London is the sponsor of this research and is responsible for looking after your information. We will keep all information about you safe and secure by:

- Data management plans have been created and reviewed in line with Imperial's Information Governance Policy Framework. This covers the collection, movement, processing and storage of the data.
- Data will be stored in a dedicated secure environment that meets recognised UK security standards, including ISO 27001 certification and/or Cyber Essentials accreditation, which underpins all security measures used in this study. These measures apply to all parts of the study, including the infrastructure used by the Imperial FAIR Data Station that supports MUSICC research activities. Identifiable information will not be stored outside these secure systems and will not be shared with collaborators.
- Robust pseudonymisation has been implemented to prevent identification.
- Access controls have been implemented to ensure only key personnel can access the data.

Some of your information will be sent to our MUSICC project research partners in the UK, USA, Australia, Singapore, Belgium, Netherlands and France. They must follow our rules about keeping your information safe.

Once we have finished the study, we will keep some of the data so that we can check the results. We will write our reports in a way that ensures no-one can work out that you took part in the study.

As a university, we use personally identifiable information to conduct research to improve health, care and services. As a publicly funded organisation, we have to ensure that it is in the public interest when we use personally identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study.

Our legal basis for using your information under the General Data Protection Regulation (GDPR) and the Data Protection Act 2018, is as follows:

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- Imperial College London - “performance of a task carried out in the public interest”. Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research.

Where special category personal information is involved (most commonly health data, biometric data i.e. finger prints or facial recognition and genetic data, racial and ethnic data etc.), Imperial College London relies on scientific or historical research purposes or statistical purposes.

9.2 International Transfers

We may share data about you outside the UK for research-related purposes to:

- Where necessary, to provide access to a data processor / service provider who will utilise your personal data as instructed by us.
- Where necessary, to share with a third-party organisation / collaborator (MUSICC partners) who are also involved in the study.

If this happens, we will only share the data that is needed. We will also make sure you can’t be identified from the data that is shared where possible. This may not be possible under certain circumstances – for instance, if you have a rare illness, it may still be possible to identify you. If your data is shared outside the UK, it will be with the following sorts of organisations:

- Our MUSICC project partners who analyse your data.

We will make sure your data is protected. Anyone who accesses your data outside the UK must do what we tell them so that your data has a similar level of protection as it does under UK law. We will make sure your data is safe outside the UK by doing the following:

- Some of the countries your data will be shared with have an adequacy decision in place. This means that we know their laws offer a similar level of protection to data protection laws in the UK.
- We use specific contracts which stipulate that personal data must maintain the same level of protection when outside the UK as it has within the UK. For further details, visit the Information Commissioner’s Office (ICO) website - www.ico.org.uk.
- We do not allow those who access your data outside the UK to use it for anything other than what our written contract with them says.
- We need other organisations to have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your data against accidental loss and unauthorised access, use, changes or sharing.
- We have procedures in place to deal with any suspected personal data breach. For further details about UK breach reporting rules, visit the Information Commissioner's Office (ICO) website - Personal data breaches: a guide | ICO.

9.3 Sharing your information with others

We will only share your personal data with certain third parties for the purposes referred to in this participant information sheet and by relying on the legal basis for processing your data as set out above.

- Other Imperial College London employees (including staff involved directly with the research study or as part of certain secondary activities, which may include support functions, internal audits, ensuring accuracy of contact details etc.), Imperial College London agents, contractors and service providers (for example, suppliers of printing and mailing services, email communication services or web services, or suppliers who help us carry out any of the activities described above). Our third-party service providers are required to enter into data processing agreements with us. We only permit them to process your personal data for specified purposes and in accordance with our policies.

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- The following Research Collaborators/Partners in the study:
    - This study is part of the MUSICC project, an international research programme that aims to better understand immunity in the respiratory tract and support the development of improved vaccines and treatments for COVID-19. The MUSICC project involves researchers and clinicians from multiple research and academic institutions across the UK, USA, Australia, Singapore, Belgium, the Netherlands and France. As described above, some of your pseudonymised research data and, where necessary, biological samples may be shared with these partners for research purposes. You will not be directly identified from any information shared. A full list of partners for the MUSICC project can be found here: https://www.musicc.org/our-team/

9.4 Potential use of study data for future research

When you agree to take part in a research study, the information collected either as part of the study or in preparation for the study (such as contact details) may, if you consent, be provided to researchers running other research studies at Imperial College London and in other organisations which may be universities or organisations involved in research in this country or abroad. Your information will only be used to conduct research in accordance with legislation including the GDPR and the UK Policy Framework for Health and Social Care Research.

This information will not identify you and will not be combined with other information in a way that could identify you, used against you or used to make decisions about you.

9.5 Commercialisation

Samples and/or data from the study may also be provided to organisations not named in this participant information sheet, e.g. commercial organisations or non-commercial organisations, for the purposes of undertaking the current study, future research studies or commercial purposes such as development by a company of a new test, product or treatment. We will ensure that your name and any identifying details will NOT be given to these third parties; instead, you will be identified by a unique study number with any sample / data analysis having the potential to generate 'personal data'.

Aggregated (combined) or anonymised data sets (all identifying information is removed) may also be created using your data (in a way which does not identify you individually) and be used for such research or commercial purposes where the purposes align to relevant legislation (including the GDPR) and wider aims of the study. Your data will not be shared with a commercial organisation for marketing purposes.

9.6 What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep and use information about you that we already have.
- You have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.
- If you choose to stop taking part in the study, we would like to continue collecting information about your health from your medical records. If you do not want this to happen, tell us and we will stop.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

9.7 Where can you find out more about how your information is used?

You can find out more about how we use your information, including the specific mechanism used by us when transferring your personal data out of the UK.

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the study team

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- by sending an email to Covid19-challenge@paediatrics.ox.ac.uk
- by ringing us on 01865 611 424/ 07990 431 010
- by going to our website pages https://www.jenner.ac.uk/volunteer/consent-and-withdrawal.

10 Complaints

If you wish to raise a complaint on how we have handled your personal data, please contact the study team first by sending an email to Covid19-challenge@paediatrics.ox.ac.uk or by ringing us on 01865 611 424/07990 431 010.

Following our response, if you are not satisfied, please contact Imperial College London's Data Protection Officer via email at dpo@imperial.ac.uk , via telephone on 020 7594 3502 and/or via post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ.

If you remain unsatisfied with our response or believe we are processing your personal data in a way that is not lawful, you can complain to the Information Commissioner's Office (ICO) via www.ico.org.uk. Please note the ICO does recommend that you seek to resolve matters with the data controller (us) first before involving them.

11 What will happen to the results of the study?

A description of this study will be available on an online database of clinical research e.g., http://www.clinicaltrials.gov. This will not include information that could identify you. At most, the registry will include a summary of the results approximately one year after the trial has ended.

If any results or publications are made publicly available during your participation in the trial, the study team will inform you where you can read these or provide you with a lay summary and/or copy. If any results or publications are made publicly available after you have completed the trial, information about these can be found on https://www.jenner.ac.uk/about/news. You will not be identified in any report/publication. There is also an optional statement on the consent form for you to agree to the study team contacting you after you have completed the study to send you relevant publications.

12 Who is organising and funding the research?

This study is sponsored by Imperial College London and forms part of the MUSICC project. The MUSICC project is led by Imperial College London and co-funded by the European Union's Horizon Europe Programme and the Coalition for Epidemic Preparedness Innovations (CEPI). https://www.musicc.org/

13 Who has reviewed this study?

The South Central Oxford A Research Ethics Committee (REC) has looked at the details of this study and have given it a Favourable Opinion. This is an independent group of experts and non-experts set up by the NHS Health Research Authority to review the ethics of this research.

14 Contact for further information

If you have any questions about taking part in this research study, please contact the study team:
Principal Investigator: Professor Helen McShane
Email: Covid19-challenge@paediatrics.ox.ac.uk
Phone: 01865 611 424/ 07990 431 010

If it is an emergency, please use the telephone number provided to you on the Emergency Contact Card to contact the study doctor as soon as you can.
Thank you for taking the time to read this information sheet. You will be given a copy of this information sheet, along with a copy of the signed Informed Consent Form, for you to keep.

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15 APPENDICES

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APPENDIX 1. Schedule of Study Activities

Study Phase			Quarantine																							
Study Day	Pre-screening	Screening (D-90 to D-3	D-2	D-1	D0 Pre	D0 Challenge	D0 Post	D1	D2	D3	D4	D5	D6	D7	D8 Uninfected	D8 Infected	D9 Uninfected	D9 Infected	D10 Uninfected	D10 Infected	Extended stay days	D14 (+/- 1 day)	D28 (+/- 5 days)	D90 (+/- 14 days)	D180 (+/- 21 days)	Early withdrawal
Written informed consent	X	X																								
Eligibility criteria review and medical & medication history	X	X	X		X																					
Height & weight, BMI	X																									
PHQ-9 and GAD-7 Mental health questionnaires		X	(X)												(X)					(X)	(X)					
Urine tests		X	X		X																					
Physical examination		X	X		(X)		(X)	(X)	(X)	(X)	(X)	(X)	(X)	(X)	(X)	(X)	(X)	(X)	(X)	(X)	(X)	(X)	(X)	(X)	(X)	(X)	(X)
Vital signs (HR, RR, SBP, DBP, SpO_2) and temperature	X	X	X	X	QDS			QDS	QDS	QDS	QDS	QDS	QDS	QDS	X	QDS	X	QDS	X	X	X	X	X	X	X	X
12-lead ECG		X	X								X			X					(X)	(X)		(X)	(X)	(X)	(X)	(X)
MRC Dyspnoea Scale +/- Spirometry			X																							
Chest X-ray		X																								
Symptom diary cards				TDS	TDS			TDS	TDS	TDS	TDS	TDS	TDS	TDS	TDS	TDS	TDS	TDS	X	X	TDS	X	X	X	X	(X)
Challenge Virus inoculation						X																				
Discharge from quarantine															X					X						
Sero-screening sample (SARS-CoV-2 antibodies) (mLs)	X	(X)	X																							
Safety bloods		X	X							X		X		X								X	X		X	X
Research bloods			X		X		X	X		X		X		X					X	X		X	X	X	X	
Respiratory PCR pathogen screen			X																							
Nasosorption	(X)	(X)	X2BD		X2		(X2)	X2BD	X2BD	X2BD	X2BD	X2BD	X2BD	X2BD	X2	X2BD	X2	X2BD	X2	X2	X2BD	X2	X2	X2	X2	X2
Mid-turbinate swab			X					X	X	X	X	X	X	X	(X)	X	(X)	X	(X)	X	X					
Inferior turbinate swab			X2					X2		X2		X2		X2					X2	X2		X2	X2	X2	X2	X2
Nasopharyngeal swab		(X)	X					X		X		X		X					X	X		X	X	X	X	X
Throat swab			X					X	X	X	X	X	X	X	(X)	X	(X)	X	(X)	X	X					
Lateral flow test			X					X	X	X	X	X	X	X	X	X	(X)	X	(X)	X	X					
Facemask sampling			X				(X)	X	X	X	X	X	X	X		X		X		(X)	X					
Environmental sampling			X					X	X	X	X	X	X	X		X		X		(X)	X					

Key:
X = occurs on this day at least once per day/visit
(X) = is either optional to participants or occurs at the investigators discretion
X2 = two measurements/samples at the same timepoint

BD = twice daily
TDS = three times daily
QDS = four times daily
X2BD = two measurements/samples twice daily

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Appendix 2. Participant Payments

This is when you will be paid for each part of the study:

Milestone	Amount	Paid by
Paid after pre-screening visit	£40	Screening Site
Paid after screening visit	£125	Screening Site
Paid after discharge from quarantine	£2,070 *(plus any additional days stayed in quarantine at £200 per day, if applicable)*	Quarantine Site
Paid after the final Day 180 visit	£1,700	Follow Up Site
If applicable: Paid after discharge from quarantine for reserve participant payments	See Table 3	Quarantine Site
If applicable: Travel to and from quarantine will be paid after receiving receipts	Cost incurred up to the maximum amount specified in Table 3.	Screening site

Please be aware that it can take around 10 to 12 weeks for your payment to be processed and appear in your account. If you do not complete the study, you will receive payment in line with the visits you attend and time spent in quarantine.

We will not pay tax or National Insurance from the money due to you. It is your responsibility to pay these and to check how any compensation received from taking part in the study affects any state benefits to which you are entitled. Contact HM Revenue & Customs for information (http://www.hmrc.gov.uk/ or telephone 0300 200 3300). Please note that there are some situations where we are required to tell the authorities about your payments if we are asked to.

Payments will be made to reserve participants as follows:

Reserve Participants	Amount
Discharged on Day –2 (pm)	£145
Discharged on Day –1 (am)	£290
Discharged on Day –1 (pm)	£410
Discharged on Day 0 (am)	£530

You can claim for travel expenses if you are travelling to a quarantine site that was not the site you were screened at:

Quarantine Site	Screening Site	Travel expenses limit for admission AND discharge journeys (total)
University of Oxford	Imperial, London	£200 maximum
	Guy's and St Thomas', London	£200 maximum
	Southampton	£200 maximum
	Liverpool	£200 maximum
	University of Oxford	£0
Royal Free Hospital NHS Trust, London	Imperial, London	£0
	Guy's and St Thomas', London	£0
	Southampton	£200 maximum
	University of Oxford	£200 maximum
	Liverpool	£200 maximum
Liverpool Human Challenge Facility	Imperial, London	£200 maximum
	Guy's and St Thomas', London	£200 maximum
	Southampton	£200 maximum
	University of Oxford	£0

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You must provide receipts for all journeys with no exceptions. You must travel in standard classes only (not First Class). If you leave quarantine on Day 8 and return for Day 9 and 10 visits, travel for those visits and follow-up appointments will not be reimbursed. Reimbursement is limited to one journey into quarantine and one journey out.

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