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Quarantine Information Sheet: COV-CHIM01

For Quarantine stays at the Experimental Medicine Clinical Research Facility, Churchill Hospital

Table of Contents

1. Introduction	2
2. Before your admission to the quarantine unit.....	2
Preparing for the quarantine.....	2
Medications.....	3
Self-isolation prior to admission	4
3. How long will I need to stay in the quarantine unit?.....	5
4. What are the rooms like?	6
5. What is an isolation room?	7
6. What can I bring with me?	8
7. What food and drink will I receive during my stay?.....	8
8. What procedures and tests will be carried out during my stay?	9
How will I be transferred from the quarantine unit to the main hospital for my CT scan?.....	9
9. How can I look after my mental health during the quarantine stay?	10
Table of procedures during quarantine	11
10. What if I wish to withdraw from the study during the quarantine period?.....	12
11. What happens once I am discharged from the quarantine unit?	13
Table of procedures during the follow up phase	15
12. Other frequently asked questions.....	16
Do you provide bedding, towels and toiletries?.....	16
Do you provide laundry service?	16
Can I have visitors during my stay?	16
Can I interact with other volunteers during my stay?	16
What rules do I need to follow during my stay?	16
13. Daily planner.....	18
14. Resources	23
Wellbeing:.....	23
Exercise:.....	23
E-books:	23

E-Learning:.....	23
Other:	23

1. Introduction

Dear volunteer,

This information sheet is designed to accompany the volunteer information sheet entitled “Participant Information Sheet: COV-CHIM01, SARS-CoV-2 challenge study in healthy adults” to provide supplementary information about your stay in the quarantine unit. It is important that you take the time to read and understand the information in this sheet carefully and discuss it with friends, relatives and your GP (General Practitioner), if you wish.

Ask us if you would like more information, or if anything is not clear. Take time to decide whether you wish to take part.

Volunteer Recruitment Coordinator
Covid19-challenge@paediatrics.ox.ac.uk

2. Before your admission to the quarantine unit.

You will need to inform the study team if:

- There are any changes to your health or you become unwell before your planned admission to the quarantine unit.
- If you are planning to start any new medications that you have not told us about at your screening visit.
- If there are any changes to your availability for the study and you are no longer able to commit to the full quarantine period on the dates you have been booked.

Preparing for the quarantine

Once you have had confirmation from the study team that you are eligible for the study and you have agreed dates for your quarantine admission, one of the study nurses will give you a call to discuss your stay at the quarantine unit and create a personalised care plan for you. We would like, where possible, to try to meet your expectations, help you create a daily routine

that works for you and the study team and to ensure that you have a pleasant stay in the quarantine unit.

We will discuss with you the following:

- ✓ Your dietary requirements.
- ✓ The type of daily activities you are planning to do during your stay.e.g; you might be planning to study or work remotely.
- ✓ The type of leisure activities you might like to do e.g; you might want to bring some books, puzzles or crafts, and/or watch movies on your device.
- ✓ The level of support you have from family and /or friends and any specific arrangements you might need to make before the quarantine e.g childcare, pet sitting etc.
- ✓ Your daily routines e.g sleeping routine.
- ✓ Your plans to keep active during your stay e.g yoga, gentle exercise etc.
- ✓ Your self-care and any personal belongings you will need to bring to the quarantine unit.
- ✓ If you need to stop any medications and/or supplements prior to the quarantine and/ or if you need to bring any medications with you to the quarantine unit.

In section 6 '*What can I bring with me*' we provide you with a list of essential items you will need to bring for your stay.

Medications

Some over-the counter, prescribed medications and supplements are prohibited during the study and need to be stopped prior to the quarantine stay to allow for a 'wash out period'. This is to ensure that these are no longer present in your body prior to the challenge.

A brief summary of some of the medications which are not permitted prior to the challenge date is shown in *table 1*. This is not an exhaustive list so please do check with the study team regarding any medications that you take including over the counter medications and supplements.

Before your admission to the quarantine unit, the study doctor/nurse will provide you with personal advice about medications if you require.

Table 1- Medications not permitted prior to the challenge

Medication	When to stop prior to the challenge date
Steroid containing medications (steroids used as a cream or ointment are allowed)	6 months
Antiviral drugs	6 months
Live Vaccines	30 days
Non-live vaccines (including any COVID-19 vaccine)	21 days
Any medication or product (prescription or over-the-counter), for symptoms of nasal congestion or respiratory tract infections including nasal steroids	30 days
Hay fever medications	7 days

Self-isolation prior to admission

To ensure you haven't been infected with COVID-19 in the community we ask you to follow current government social distancing guidance. For further information please see the following website:

[Coronavirus \(COVID-19\): Meeting with others safely \(social distancing\) - GOV.UK \(www.gov.uk\)](https://www.gov.uk/guidance/coronavirus-covid-19-meeting-with-others-safely-social-distancing)

Immediately prior to your admission we will perform a COVID-19 swab. This visit will occur 3 to 4 days before you come into the quarantine unit (5 or 6 days before the planned challenge date). We then ask that you self-isolate at home after the swab has been performed and until you come into the quarantine unit. This is an important measure both for your own safety and to ensure the research data is accurate (we would not want to inadvertently dose you with further virus if you were already infected). We would also request that you inform us if you develop any symptoms prior to coming into the quarantine unit or if you are told to self-isolate by Test and Trace as a result of close contact with someone with COVID-19. In this situation, if it would fit with our study schedule we would delay your enrolment or in some cases we may have to withdraw you from the study.

3. How long will I need to stay in the quarantine unit?

The minimum stay in the quarantine unit is 17 days. You will need to be admitted into the quarantine unit on day -2 (day minus 2), this is 2 days before the planned date of the challenge. This is because we want to make sure you remain well and you are still eligible to take part in the study.

We will perform some tests, as explained in the Study Participant Information Sheet. We will take a deep nasal swab to make sure it is still negative for COVID-19 and a selection of other viruses.



Deep nasal swab

You will be discharged at day 14 post-challenge (after 17 days total) at the discretion of the study doctor, if you are feeling well and you are no longer shedding live virus and therefore are not contagious.

You should be prepared that there is a chance you may need to stay longer in the quarantine unit, if you are still shedding live virus on day 14. This will be discussed with you if necessary.

We know that the average incubation period for the virus to show infection is 5 days after contact and that most individuals stop shedding live virus after 9 days. We therefore hope that you will be ready to leave by day 17. **However, you should be prepared to stay for longer.**

4. What are the rooms like?

There are five quarantine rooms at the Experimental Medicine Clinical Research Facility (EMCRF) at the Churchill. The quarantine rooms have appropriate ventilation systems in place to prevent the spread of infection. We explain what this means in *section 5 “What is an isolation room”*. Each room has an ensuite bathroom, a hospital bed, an armchair and a bed table. There will be no cooking facilities; meals will be provided by staff. Items in the isolation rooms are kept to a minimum. The following facilities will be available in each room: a small fridge, a kettle, a selection of teas and coffee and a hairdryer is available should you need it.



Pictures of the isolation room

5. What is an isolation room?

An isolation room is commonly used in hospitals for patients with airborne infections to prevent any spread from room to room. It includes a robust ventilation system that prevents contaminated air from leaving the room. The ventilation system allows air to flow into the isolation room but not escape. This is achieved by creating a negative pressure inside the isolation room (pressure lower than the surroundings), or a positive pressure (pressure higher than the surroundings) inside an anteroom (or lobby room) that leads to the isolation room. **In order to maintain this difference in pressure you will be unable to open windows during your stay in the room.**

A participant known to have contracted COVID-19 can spread the virus person-to-person. This means between people who are in close contact with one another (within about 6 feet), or through respiratory droplets produced when an infected person coughs or sneezes. These droplets can land in the mouths or noses of people who are nearby or possibly be inhaled into the lungs. By being in an isolation room during the quarantine period, we minimise the risk of spreading the COVID-19 virus to other people. The research team will wear protective clothing every time they enter your room. This will depend on the study procedure being performed but will always include apron, gloves, a face mask and eye protection. For the challenge procedure they will additionally wear a visor or hood to cover their faces. We will also ask you to wear a face mask during any interaction with the study team. This is to reduce even further any potential risk of transmission to the study staff.



Pictures of staff wearing protective clothing

6. What can I bring with me?

Our team need space to carry out their work, so there may not be room for big items like TVs or desktop computers, but most things like laptops, electronic tablets and any small items are very welcome.

A quick call to us before your stay to check acceptable items is recommended.

Here is a list of things you might want to bring:

✓ **Toiletries including:**

- Toothbrush/ tooth paste
- Shampoo and shower gel
- Other personal toiletries e.g. Body cream, deodorants, hair brush, earplugs, sleep aids etc.
- (Optional for female volunteers) Tampons and/or sanitary towels

✓ **Enough clothing for at least 17 days, including:**

- Comfortable outfits
- A cardigan, robe, hoodie or similar to keep you warm
- Underwear
- Pyjamas
- Comfortable shoes and/or slippers

✓ **Personal devices** e.g. phone, laptop, tablet and charging cables (wifi and plug sockets will be available).

✓ **Leisure items**, such as books, magazines, puzzles, knitting kits/ other craft materials, a yoga mat etc.

If you forget anything, friends and family can drop items off at the quarantine unit for you (via study staff).

7. What food and drink will I receive during my stay?

You will receive three meals a day as well as a variety of snacks. We have a choice of foods available, including vegetarian/vegan options. We will discuss your dietary requirements prior

to your admission to the quarantine unit. Please let us know in advance of any special dietary requirements or preferences so we can plan ahead of your admission.

Water will always be available and tea and coffee is available to order or you may also use the kettle available in the room. As hygiene and cleanliness are essential, we can't allow you to bring your own food or drink to the quarantine unit. However, we are very happy to discuss any preferences with you before your planned admission.

8. What procedures and tests will be carried out during my stay?

As described in the study Participant Information Sheet (PIS), the research team will carry out a number of tests and procedures from the day of your admission into the quarantine unit. Depending on the test or procedure, these are carried out once a day, several times a day and/or on specific days. You will undergo a second Cardiac MRI (or echocardiogram) on the day of discharge, or after discharge prior to your 1 month follow up visit (depending on availability) if you develop COVID during the quarantine stay.

The “*table of procedures during quarantine*” on page 11, shows you what procedures are being carried out each day during the quarantine period. You might have additional tests, such as extra blood tests if you become unwell. At the end of this document, we have created a daily planner, which will be discussed with you on admission and we hope will help you to organise your daily routine around the study requirements.

How will I be transferred from the quarantine unit to the main hospital for my CT scan?

On day 5 post-challenge you will be transferred to the radiology department at Churchill Hospital for your CT scan. You will be accompanied by a member of the study team.

In order to avoid any risk of COVID transmission to other people, you will be required to wear a face mask. You may also be asked to wear other clothing such as an apron or similar, during the CT scan procedure.

You may need a second CT scan on day 11 post-challenge, if you have shown evidence of infection after your Day 5 scan (ongoing positive results for virus from your nose/mouth swabs or a strong suspicion based on other investigations or symptoms or signs that you may have).

9. How can I look after my mental health during the quarantine stay?

It's only natural that you may feel anxious about taking part in this study. You may be concerned about some of the study procedures or about having to self-isolate in an unfamiliar environment away from your usual support networks. It is important you consider the effect of the study on your mental health prior to taking part. We will work with you to think about ways in which we can safeguard your mental health whilst participating in this study. We have included a list of well-being resources and activities that you may wish to undertake during the quarantine period (Section 14). Additionally, we would recommend you arrange regular contact with your family and friends by telephone or video call as a means of added support.

We will be asking you to complete regular mental health questionnaires as a means of monitoring your mental health during the quarantine period but if you have any concerns during your quarantine stay (or at any point in the study period) we actively encourage you to talk to the study team. If we become concerned about your mental health we would discuss whether or not we need to adapt study procedures or withdraw you from the study. Additionally, if necessary we may refer you on for additional support via psychological services.

Table of procedures during quarantine

Procedures / Day	Day -2	Day -1	Day 0	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14^	
Physical examination																		Frequency of procedures:
Weight																		<div></div> Not required
Blood tests																		<div></div> Only if required
Vital signs																		<div></div> A 'one off' procedure
Urine tests																		<div></div> Once a day
Pregnancy test (blood test*/urine test)	*																	<div></div> Twice a day
SARS-CoV-2 challenge																		<div></div> Four times a day
ECG																		
Throat and nose swab																		
Deep nasal swab	x3 swabs				X2			X2		X2				X2			X2	
Mask wearing																		
Smell test																		
Nose strips (nasosorption)																		
Health questionnaires																		
Cognitive tests																		
eDiary																		
CT scan																		
MRI scan or echocardiogram(*)																	(*)	
MRI scan/Echocardiogram (*) on day of discharge, or after discharge but before 1 month follow up visit. ^Day 14 procedures shown if day of discharge																		

10. What if I wish to withdraw from the study during the quarantine period?

You are free to withdraw from the study at any time, however If you decide to withdraw your consent and 'leave the study' during the quarantine phase, you will be very strongly encouraged to remain in the quarantine unit until you are no longer contagious. This is for both your own safety and that of others whom you could infect as a contact. In this situation, we would continue optionally to offer you all procedures considered important for safety purposes but would stop any research procedures. This would include:

- Regular vital signs
- Medical review of any symptoms
- Safety blood tests (but not research ones)
- Ronapreve rescue therapy (if being offered)

Remaining in the unit would therefore allow close follow-up by the study medical team and receipt of the rescue therapy (if being offered). If you have to leave the quarantine unit before you have been formally discharged, you will be legally required to self-isolate as per the latest government guidance and we are legally obliged to inform the NHS Test & Trace system so that they can ensure adequate self-isolation.

In the event that you decide to leave the unit early:

- You will be advised about hand-washing and other infection control measures by the study medical team.
- You will be transported home in private transport, and you will need to wear protective equipment (e.g face mask etc) during the trip.
- If you return home and there are other people in your household, they will also need to self-isolate according to government guidelines; as they are at risk of picking up infection from you. This will be explained to you before you leave.
- You may not be eligible to receive the rescue therapy with Ronapreve (if being offered) if your withdrawal is prior to the planned date of treatment.
- With your agreement, you will be contacted daily by the study staff (i.e. study doctor or nurse) via phone call to check on your health and to remind you of self-isolation requirements until the study doctors are satisfied that daily follow up can end.

11. What happens once I am discharged from the quarantine unit?

Prior to discharge, you will receive a thermometer (we will provide this), training regarding the signs and symptoms of potential complications of infection, and how and when to contact study staff. You will be asked to record your temperature on an electronic diary daily until your first follow up visit after discharge from the quarantine unit (1 month follow up visit after virus infection). If you develop a fever or develop new or worsening symptoms of infection, we may ask you to attend for evaluation and repeat testing for the SARS-CoV-2 virus. If you test positive for the virus once more we may ask you to self-isolate at home. **Please refer to section 9 ‘What if I develop new suspected COVID symptoms after discharge from quarantine?’ of the study Participant Information Sheet for full information.**

You will be asked to contact the study team if after discharge you:

- **Develop any new symptoms concerning for COVID-19**
- **Have any positive tests for COVID-19 (outside of the study tests)**
- **Receive a COVID-19 vaccine (please refer to section 8.3 of study Participant Information Sheet for full details)**
- **Receive any medical care outside of the study (e.g. GP or hospital attendances)**

Following discharge from the quarantine unit, the clinical team will monitor your symptom diary. This is to be completed daily from discharge until your 1 month follow up visit and then weekly until your 3 month follow up visit. The study team may contact you (telephone or email) to make sure you are well or to clarify any symptoms from your e-diary. Additionally, you will be provided with a 24- hour contact number to get through to a study doctor should you have any concerns.

You will return for clinic appointments at 1,2,3,6 and 12 months after challenge at the Centre for Clinical Vaccinology and Tropical Medicine (CCVTM) at the Churchill Hospital (where you attended your screening visit) so that we can carry out more tests and procedures to check your health and to collect samples for research. The “*table of procedures during follow up phase*” on page 15, shows you what procedures are being carried out at each follow up visit. **We will send you an email or text reminder before each of these appointments.**

You can use the table below to write the dates and times of these visits:

Visits- post challenge	Date	Time
1 month (Day 28)		
2 months (Day 56)		
3 months (Day 84)		
6 months (Day 168)		
12 months (Day 365)		

Table of procedures during the follow up phase

Procedures / Visit	1 month	2 months	3 months	6 months	12 months
Physical examination					
Blood tests					
Vital signs					
Urine tests					
ECG					
Pulmonary Function Test					
Throat and nose swab					
Deep Nasal swab (2-3)*					
Smell test					
Nose strips (nasosorption)					
Health questionnaires					
Cognitive tests					
Weekly E-Diary (review)					

Schedule of procedures:	
	Not required
	Only if clinically required
	Required

*Deep nasal swabs will be performed at follow up visits in all volunteers who have demonstrated evidence of SARS CoV-2 positivity during the study. A single deep nasal swab may be performed to look for bacteria or viruses that cause cold or flu symptoms if these are present.

12. Other frequently asked questions

Do you provide bedding, towels and toiletries?

Fresh hospital bedding is provided as needed and is changed daily. For comfort, you might prefer to bring your own bedding (e.g pillows, duvet). We ask volunteers to bring their own towels and toiletries, but if something is forgotten, we have a small supply available.

Do you provide laundry service?

We don't offer a laundry service, so please pack enough clothes for the duration of your stay. Please also make sure you bring clothes to keep you warm, as the rooms are temperature controlled.

Can I have visitors during my stay?

You will not be able to receive any visitors during your stay in the quarantine unit. This is to prevent spreading COVID-19 infection to others. You can contact your relatives and friends during your stay in the quarantine unit, via phone and/or video call using your personal device. Additionally, they can drop off supplies for you (e.g. toiletries) with the study team if needed.

Can I interact with other volunteers during my stay?

There will not be any opportunities for interaction with other volunteers as this could expose you to a further dose of the virus if they are contagious and impact the study data. You will only have face-to-face interaction with the study team during your stay at the quarantine unit. The study team will endeavour to make your stay at the quarantine unit as pleasant an experience as possible. Also, in section 14 of this booklet you have a list of online resources that you might find useful during your stay at the quarantine unit.

What rules do I need to follow during my stay?

Whilst, we want you to feel comfortable during your stay we do ask that for your safety and the consideration of other building users you comply with any requests from study staff. This includes keeping your room clear of obstructions to enable performance of study procedures.

Additionally, showing consideration by limiting excessive noise e.g. loud music during unsociable hours.

We are more than happy to discuss any plans you may have during the study period before you come in.

We hope you found this information booklet useful. Should you need further information, please do not hesitate to contact the study team on:

Covid19-challenge@paediatrics.ox.ac.uk

13. Daily planner

Time	Day -2 Admission Day	Day -1	Day 0 Challenge Day	Day 1
6:00 AM				
7:00 AM				
8:00 AM				
9:00 AM				
10:00 AM				
11:00 AM				
12:00 PM				
1:00 PM				
2:00 PM				
3:00 PM				
4:00 PM				
5:00 PM				
6:00 PM				
7:00 PM				
8:00 PM				
9:00 PM				
10:00 PM				

Time	Day 2	Day 3	Day 4	Day 5
6:00 AM				
7:00 AM				
8:00 AM				
9:00 AM				
10:00 AM				
11:00 AM				
12:00 PM				
1:00 PM				
2:00 PM				
3:00 PM				
4:00 PM				
5:00 PM				
6:00 PM				
7:00 PM				
8:00 PM				
9:00 PM				
10:00 PM				

Time	Day 6	Day 7	Day 8	Day 9
6:00 AM				
7:00 AM				
8:00 AM				
9:00 AM				
10:00 AM				
11:00 AM				
12:00 PM				
1:00 PM				
2:00 PM				
3:00 PM				
4:00 PM				
5:00 PM				
6:00 PM				
7:00 PM				
8:00 PM				
9:00 PM				
10:00 PM				

Time	Day 10	Day 11	Day 12	Day 13
6:00 AM				
7:00 AM				
8:00 AM				
9:00 AM				
10:00 AM				
11:00 AM				
12:00 PM				
1:00 PM				
2:00 PM				
3:00 PM				
4:00 PM				
5:00 PM				
6:00 PM				
7:00 PM				
8:00 PM				
9:00 PM				
10:00 PM				

Time	Day 14			
6:00 AM				
7:00 AM				
8:00 AM				
9:00 AM				
10:00 AM				
11:00 AM				
12:00 PM				
1:00 PM				
2:00 PM				
3:00 PM				
4:00 PM				
5:00 PM				
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7:00 PM				
8:00 PM				
9:00 PM				
10:00 PM				

14. Resources

Wellbeing:

Tips for everyday living:

<https://www.mind.org.uk/information-support/tips-for-everyday-living/>

<https://www.dpt.nhs.uk/resources/recovery-and-wellbeing/five-ways-to-wellbeing>

<https://www.nhs.uk/oneyou/every-mind-matters/sleep/>

<https://www.nhs.uk/mental-health/self-help/guides-tools-and-activities/mental-wellbeing-audio-guides/>

Meditation, mindfulness resources:

<https://www.headspace.com/>

<http://www.freemindfulness.org/>

<https://www.oxfordmindfulness.org/learn-mindfulness/resources/>

<https://www.innerspace.org.uk/>

Beating the isolation blues self-help pack – This [useful pack](#) was developed by one NHS Trust's psychologists and is aimed at people of all ages. It can be used daily or when you're experiencing a dip in your mood, are bored or frustrated.

Exercise:

<https://www.nhs.uk/better-health/get-active/home-workout-videos/>

<https://www.nhs.uk/conditions/nhs-fitness-studio/>

E-books:

<https://www.readanybook.com/>

E-Learning:

<https://world-geography-games.com/>

<http://www.bbc.co.uk/languages/>

<https://www.openculture.com/>

Other:

A huge list of free resources including virtual tours, online courses, games, music, nature, arts, exercise and well-being: <https://chatterpack.net/blogs/blog/list-of-online-resources-for-anyone-who-is-isolated-at-home>

<https://www.louvre.fr/en/visites-en-ligne>