**ISARIC/WHO Clinical Characterisation Protocol UK**

**SERIAL SAMPLING OF CONVALESCENT PATIENTS**

**INFORMATION SHEET & CONSENT FORM FOR ADULT PATIENTS - IRAS Ref. 126600**

7th May 2020. Version 9.3

Local lead investigator: **[\*\*\*local\_investigator\_name\*\*\*]**

You are being asked to take part in a research study involving people with an infection such as the one you have recently recovered from. This information is being given to you to explain why the study is being done, what it involves and why we would like you to take part. Once you have read it, one of our team will go through the information with you. Please ask us if there is anything that is not clear. Agreement to be part of the study is completely voluntary and will not affect your ongoing medical care in any way. You may have already generously participated in a study called the ISARIC/WHO Clinical Characterisation Protocol whilst you were in hospital – this is part of the same research.

**What is this study about?**

We need to understand more about how the immune system responds to infections such as the one you have just recovered from. This includes finding out which parts of the immune system are involved in making people immune, and how long immunity lasts for.

**What will happen if I take part in this study?**

We will collect information about you, including details of the infection you had, the results of tests done while you were unwell, other medical problems you may have and the medicines you take.

We will contact you and ask you to attend a clinic appointment with one of the researchers. At this appointment we will take blood samples (up to 42.5mls, 7 teaspoons) and swabs from your mouth and nose. We will invite you to return for these samples to be repeated up to every month for up to two years.

**What will happen to my information?**

All information about you will remain confidential. Your name and other personal details will not appear in any report, but we will share the results of analyses widely. We will record your NHS number, date of birth and postcode (to anonymously link study results to information in electronic medical records) and telephone number (to arrange follow-up appointments). With your permission, we will contact you by letter, phone call or text message. The work we do with your data is ‘a task in the public interest’. The way your data is used is carefully regulated by UK law. *We will keep the minimum personally identifiable information about you indefinitely for safety reasons and because it is a valuable record of this outbreak event.* More information about how linking to routine health data as part of this study and what this means for your data can be found at **[\*\*\*weblink to privacy statement\*\*\*]**.

**What will happen to my samples?**

The samples will be used to study immune responses to infection (which could inform the design of vaccines and medicines), to develop diagnostic tests, and set reference standards for blood tests, and to make products, including commercial products.

**What are the benefits to taking part in this study?**

There is no direct benefit to you, but the research may help others.

**What are the risks?**

A blood donation of this size is not expected to have any significant after-effects. The main drawback to you of providing blood samples is the slight discomfort or pain when samples are taken.

**Can I request that I be withdrawn from the study?**

You can withdraw from the study at any time, and don’t need to give a reason if you choose to do so. Any samples that have not already been analysed can be destroyed, if you wish.

**Will the samples be used for future research?**

With your consent, we would like to keep your contact details after the study is complete so we may ask if you are willing to participate in future studies. This is entirely optional. Your contact details would be stored electronically on a secure computer system separately from the study data. You can ask us to have your contact details removed from our database at any time.

**Where can I find more information?**

If you would like more information about the study, you can contact the Local Investigator at your hospital **[\*\*\*local\_investigator\_name\*\*\*]** or telephone the Local Research office on **[\*\*\*local\_research\_office\_phone\_number\*\*\*]**.

If you would like to know about the progress of the study or if the results of the study, you can visit our website for participants at <http://isaric.net/ccp/uk/info/>

There may be opportunities to attend events relating to the study or to join a panel of research participants who can make further contributions to this research and future research studies. We will post information about any such events on the participants’ website.

**Who is legally responsible for this study?**

All UK research needs a ‘Research Sponsor’, which in this case is the University of Oxford. The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study. NHS indemnity operates in respect of the clinical treatment which is provided. The data and materials related to this study may be inspected by regulatory authorities, including the Research Sponsor, NHS Trust(s) or public health agencies in the UK. This study has been reviewed and given a favourable opinion by the **Oxford C NHS Research Ethics Committee – reference number: 13/SC/0149**

**Who do I complain to if I am unhappy about any part of this research study?**

If you wish to complain about the way in which you have been approached, treated, or how your information is handled for this study, you should contact **[\*\*\*local\_investigator\_name\*\*\*] [\*\*\*local\_contact\_details\*\*\*]** or you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 616480, or the head of CTRG, email [ctrg@admin.ox.ac.uk](mailto:ctrg@admin.ox.ac.uk).

NHS indemnity covers the clinical treatment with which you are provided. The Patient Advisory Liaison Service (PALS) is a confidential NHS service which provides support for those who wish to make complaints or raise queries regarding the care you receive as an NHS patient. However, PALS will not provide information specifically about this research study.

**PARTICIPANT ID: \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_**

**INFORMED CONSENT FORM FOR ADULT PATIENTS**

**SERIAL SAMPLING OF CONVALESCENT PATIENTS**

7th May 2020. Version 9.3

Local lead investigator: **[\*\*\*local\_investigator\_name\*\*\*]**

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| ***PLEASE MARK YOUR INITIALS AGAINST EACH STATEMENT TO WHICH YOU AGREE:*** |  |
| I have read the information sheet for Serial Sampling of Convalescent Patients dated 7th May 2020 Version 9.3 or it has been read to me. I understand the information and have had the opportunity to ask questions about it. |  |
| I understand that my participation is voluntary and that I am free to withdraw from the study at any time, without giving any reason and without my medical care or rights being affected. |  |
| I agree to the use of my data and samples. |  |
| I give permission for my medical records and data collected during the study to be examined by the Research Sponsor (the University of Oxford), by regulatory authorities, representatives of the NHS Trust(s) or public health agencies who oversee this research. |  |
| I agree that a copy of this consent form which will include my name, address and phone number will be sent to the central study team (where it will be kept in a secure location), to allow confirmation that my consent was given and for administration of the study. |  |
| **I agree to participate in this research study.** |  |
| I agree that my **data and samples may be used for other unrelated ethically-approved research in the UK or elsewhere**.  OR IF YOU DO NOT AGREE, TICK HERE ❑ |  |
| I agree that samples taken from me, or materials or data derived from those samples, can be used to **manufacture tests, treatments or other products, including commercial products.**  OR IF YOU DO NOT AGREE, TICK HERE ❑ |  |
| I agree that my de-identified data and results of analyses, **can be shared with other scientists, including those in other countries**. OR IF YOU DO NOT AGREE, TICK HERE ❑ |  |
| I agree to be **contacted by the investigators to be invited to participate in future work, including research studies.**  OR IF YOU DO NOT AGREE, TICK HERE ❑ |  |

Participant name (PLEASE PRINT):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Participant Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: \_\_ \_\_ / \_\_ \_\_ \_\_ /\_\_ \_\_ \_\_ \_\_

Name of person taking consent (PLEASE PRINT):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of person taking consent: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_ \_\_ / \_\_ \_\_ \_\_ /\_\_ \_\_ \_\_ \_\_

**Witnessed Consent**  
*If the consenting person cannot read the form:* I have no interest or involvement in this research study. I have been introduced to the participant and identified as a witness to their consent. I attest that the information concerning this research was accurately read and explained to the participant in language they can understand. I attest that informed consent was freely given by the participant.

Witness name (PLEASE PRINT): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of witness: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_ \_\_ / \_\_ \_\_ \_\_ /\_\_ \_\_ \_\_ \_\_

Contact details of the participant:

Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Phone number \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_

**Thank you for your contribution to this important global research activity.**