**ISARIC/WHO Clinical Characterisation Protocol UK – IRAS Ref. 126600/ 279826**

**SUMMARY** **INFORMATION SHEET & VERBAL (TELEPHONE) CONSENT FORM FOR ADULT PATIENTS - DATA ONLY**

30th August 2022. Version 10.2
Local lead investigator: **[\*\*\*local\_investigator\_name\*\*\*]**

***This summary information sheet should be used by researchers taking a verbal declaration from an adult patient by telephone. The researcher should introduce themselves and explain the purpose for the telephone call. The discussion should cover the content detailed below. Give the patient the opportunity to ask questions.***

You are being asked to take part in a research study involving people with infection due to or exposure to an emerging pathogen (“bug”), chemical, toxin, or potentially harmful energy source of public health interest such as the one you have recently experienced.

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 care or treatment in any way.

**What is this study about?**

We need to find out more about how infections or exposures such as the one you have recently acquired affect people. By studying your case, we hope to find better ways to diagnose and manage people with the same and similar conditions.

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

We will collect information about you, including other medical problems you may have, the medicines you take, the treatment you receive and the results of tests.

You can withdraw from the study at any time, and don’t need to give a reason if you choose to withdraw.

**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/CHI number, date of birth and postcode (to link study results to information in electronic medical records) and telephone number (to arrange follow-up samples).

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. There may be need to refer to your data for related very long-term follow up studies.  For more information on how we process and protect your data, please see the full information sheet or visit [**https://isaric4c.net/privacy/**](https://isaric4c.net/privacy/)

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

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

**Can I request that I be withdrawn from the study?**

Yes, you can withdraw at any time without giving a reason and without affecting your care. Your personal identifiers and clinical data will be removed from our databases.

**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** and **Scotland A Research Ethics Committee (Ref 20/SS/0028).**

**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 Research Governance, Etrhics & Assurance (RGEA) office on 01865 616480, or the director of RGEA, email 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.

The Patient Advisory and Support Service (PASS) is a confidential service provided by the Citizens Advice Bureaux in Scotland. It can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. PASS is unable to provide information about this research study.

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

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INFORMED TELEPHONE CONSENT FORM FOR ADULT PATIENTS**
30th August 2022. Version 10.2

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| THE RESEARCHER SHOULD MARK THEIR INITIALS AGAINST EACH STATEMENT THAT IS CORRECT: |  |
| I have discussed the content of the summary information sheet above dated 30th August 2022 version 10.2 (above) with the participant. They understand the information and have had the opportunity to ask questions about it.The participant understands that their participation is voluntary and that they are free to withdraw from the study at any time, without giving any reason and without their medical care or rights being affected. |  |
| The participant gives permission for their 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. |  |
| The participant agrees that a copy of this consent form which will include their 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 their consent was given and for administration of the study. |  |
| **The participant agrees to participate in this research study.** |  |
| The participant agrees that their de-identified **data may be used for other unrelated ethically-approved research in the UK or elsewhere**. OR IF THEY DO NOT AGREE, TICK HERE ❑ |  |
| The participant agrees that their de-identified data **can be shared with other scientists, including those in other countries**.OR IF THEY DO NOT AGREE, TICK HERE ❑ |  |
| The participant agrees to be **contacted by the investigators to be invited to participate in future work, including research studies.** OR IF THEY DO NOT AGREE, TICK HERE ❑ |  |

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

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

Contact details of the participant:

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Phone number \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_

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Name of person taking verbal consent (PLEASE PRINT):

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of person taking verbal consent: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_ \_\_ / \_\_ \_\_ \_\_ /\_\_ \_\_ \_\_ \_\_