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

**SUMMARY INFORMATION SHEET & CONSENT FORM FOR TELEPHONE/REMOTE USE BY THE PROXY OF AN ADULT WITH INCAPACITY (THEIR GUARDIAN, WELFARE ATTORNEY OR CLOSEST FAMILY MEMBER) IN SCOTLAND**

**DATA AND SAMPLES**

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

***This summary information sheet should be used by researchers taking a verbal consent from a proxy (the guardian, welfare attorney or closest family member) of a potential adult participant with incapacity by telephone or other mode of remote communication. The researcher should introduce themselves and explain the purpose for the telephone call. The discussion should cover the content detailed below. Give the proxy the opportunity to ask questions.***

We are undertaking 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 recently experienced by the potential participant. We are asking you about the participation of an individual who is not able to consent for themselves, because he/she lacks the legal capacity to do so. To help decide if he/she should join the study, we would like to ask your view on whether or not you consider he/she would wish to be involved but before you decide it is important for you to understand why the research is being done and what it would involve for the participant.

Please take time to read this information carefully. One of our team will go through the information with you. Please ask us if there is anything that is not clear or if you would like more information and time to decide. Your decision is completely voluntary. The decision you make **will not** affect the participant's care or treatment in any way. When deciding, please put aside your own feelings and wishes and consider what the past and present feelings and wishes of the person you are consenting on behalf of would have been, had they been able to consent for themselves.

## What is this study about?

We need to find out more about how infections or exposures affect people. By studying the participant’s case, we hope to find better ways to diagnose and manage people with this and similar conditions.

## What will happen if they take part in this study?

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

In addition to samples normally taken as part of their medical care, other samples will be collected as well. This will include blood, mouth, nose or throat swabs or suction samples, swabs from any infected site, a sputum sample (if they are coughing up mucus), urine and stool (faeces or ‘poo’). Additional blood samples would be up to 15 ml (3 teaspoons) in volume. If specialist breathing support is required, we will take samples of lung fluid for analysis.

Video calls may be used to help in how swabs are taken f you wish. Digital photography may be used to record any skin lesions and ensure swabs are taken from the same place.

We will take the same samples twice more over the next two weeks. We will also ask if they are willing to return 28 days after discharge for a further set of samples.  Each blood sample will take 42.5mls (7 teaspoons) or less (depending on the participant’s weight).

All of these samples are voluntary. The participant or you as their proxy can withdraw them from the study at any time, and don’t need to give a reason for this.

## What will happen to their information?

All information about the participant will remain confidential. Their name and other personal details will not appear in any report, but we will share the results of analyses widely. We will record their CHI number, date of birth and postcode (to anonymously link study results to information in electronic medical records) and telephone number (to arrange follow-up samples). With permission, we will contact the participant by letter, phone call or text message. The work we do with data is ‘a task in the public interest’. The way their data is used is carefully regulated by UK law. We will keep the minimum personally identifiable information about the participant 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 data, please see the full information sheet or visit [www.isaric4c.net/privacy](http://www.isaric4c.net/privacy).

## What will happen to their samples?

We will use the samples to discover how they respond to infection, how treatments work and to develop new tests or treatments. As part of this, we will analyse their genetic information (DNA) to discover why people respond differently to infections.

We will store their samples and use them for future ethically approved medical studies in the UK or elsewhere. We might use their samples to manufacture tests, treatments or other materials, including commercial products.

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

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

## What are the risks?

There is a small risk from taking the samples. Whenever possible, the samples will be taken at the same time as samples necessary for their medical care. The main drawback of donating samples is the slight discomfort or pain when samples are taken. Risk of lung damage during bronchoscopy is less than 1%.

We are doing genetic (DNA) tests to understand how genes affect infections. The results of these tests won’t affect their medical care and we will not tell them the results from these tests.

## Can I request that they be withdrawn from the study?

The participant or you as their proxy can withdraw from the study at any time without giving a reason and without affecting their care. Any samples that have not already been analysed can be destroyed, if you request this.

## Will their samples be used for future research?

We would like to keep the participant’s contact details after the study is complete so we may ask if they are willing to participate in future studies. This is entirely optional. Their contact details would be stored electronically on a secure computer system separately from the study data. You or they can ask us to have these 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 the participant’s 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 for the participant 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 the participant suffers any harm as a direct consequence of their 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 or the participant have been approached, treated, or how 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, Ethics & Assurance (RGEA) office on 01865 616480, or the director of RGEA, email ctrg@admin.ox.ac.uk.

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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**CONSENT FORM FOR TELEPHONE/REMOTE USE BY THE PROXY OF AN ADULT WITH INCAPACITY (THEIR GUARDIAN, WELFARE ATTORNEY OR CLOSEST FAMILY MEMBER) IN SCOTLAND – DATA and SAMPLES**

30th August 2022. Version 10.2

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

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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 dated 30th August 2022 version 10.2 above with the participant’s proxy. The proxy has told me that they understand the information and has had the opportunity to ask questions about it. The proxy is willing to act as proxy for the participant. |  |
| The proxy has told me that they understand that the participant’s participation is voluntary and that the participant is free to withdraw from the study at any time, without giving any reason and without the participant’s medical care or rights being affected. |
| The proxy has told me that they understand that data and samples **including DNA** from the participant will be used in this study. |
| The proxy has told me that they understand that medical records and data collected during the study could 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 proxy has told me that they understand that a copy of this declaration form which will include their name, address and phone number, and the participant’s 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 advice was given and for administration of the study. |
| **The proxy has told me that it is their consideration that the participant would be happy to participate in this research study.** |
| The proxy has told me that they understand that the participant’s **data and samples may be used for other unrelated ethically- approved research in the UK or elsewhere.**Or if they think that the participant would not want this tick here ❑ |  |
| The proxy has told me that they understand that samples taken from the participant, or materials or data derived from those samples, may be used to **manufacture tests, treatments or other products, including commercial products.** Or if they think that the participant would not want this tick here ❑ |  |
| The proxy has told me that they understand that de-identified data and results of analyses, including the whole sequence of the participant’s DNA and RNA, **will be shared with other scientists, including those in other countries**.Or if they think that the participant would not want this tick here ❑ |  |
| The proxy has told me that they understand that the participant may to be **contacted by the investigators to be invited to participate in future research studies.**Or if they think that the participant would not want this tick here ❑ |  |

Name of participant (PLEASE PRINT): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Contact details of participant

Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Phone Number: \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_

Email of participant (PLEASE PRINT): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of proxy (PLEASE PRINT): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Contact details of proxy

Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Email of proxy (PLEASE PRINT): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Relationship of proxy to participant: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

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

Person taking verbal advice from proxy (PLEASE PRINT:

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

(Research team member or health professional making the telephone call and who is trained in taking consent for this study)

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