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

**INFORMATION SHEET & CONSENT FORM FOR BEREAVED RELATIVES**

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

We are sorry to contact you at this sad time.

We are running a study called ISARIC Clinical Characterisation Protocol UK (CCP-UK) and would like your permission to use your relative’s information and samples in this research study. CCP-UK involves people who have or had an infection or been exposed to an emerging pathogen (“bug”), chemical, toxin or potentially harmful energy source of public health interest, such as the infection or exposure your relative had.

This information is being given to you to explain why the study is being done, what it involves and why we would like your permission to use your relative’s information and or samples.

Once you have read it, if there is anything that is not clear, you can ask to speak to your local investigator by calling **[\*\*\*CI/Deputy investigator study phone number\*\*\*]**.

Agreement to your relative being part of this study is completely voluntary.

**What is this study about?**

We need to find out more about how infection due to or exposure to an emerging pathogen, chemical, toxin or potentially harmful energy source of public health interest such as the one your relative recently experienced affect people. By studying your relative’s case, we hope to find better ways to diagnose and manage people with the same and similar conditions.

**What will happen if I agree for my relative’s samples to be used in this study?**

When your relative was hospitalised they had information and samples collected to help the doctors looking after them better understand their illness and how to treat them. These samples were used to inform the care your relative received, but some of their samples had a small amount that remained unused. In research, we often call this “residual material”, and we would like your permission to use these left-over samples in our research study.

We would use these residual samples to discover how people respond to infection, how treatments work and/or to develop new tests or treatments. You also have the option to decide whether or not we can use blood samples to analyse your relative’s DNA and RNA. RNA, like DNA, carries genetic information. If you agree, we will examine their DNA and RNA together with DNA and RNA from many other people to try to find out what makes some people more likely to get an infection. Some of the tests may be done in different countries.

With your permission, we will store the samples and use them for future ethically approved medical studies in the UK or elsewhere. We might also use your relative’s samples to manufacture tests, treatments or other materials, including commercial products.

If you agree to your relative’s samples being used in this study, we will compare the sample results with data that has already been collected about your relative. The information about your relative includes other medical problems they may have had, the medicines they took, the treatment they received and the results of tests they may have had. This information will help us to understand the results of their samples, and improve our understanding of these infections, including how best to treat people in future.

**What will happen to my relative’s information?**

All information about your relative and you will be kept confidential by those working on this study, and your relative’s name or other identifiers will not be used in any reports about this study. The results of the study will be shared as quickly as possible with health authorities, and doctors to help them treat patients with this infection.

UK Data protection regulation requires that we state the legal basis for processing information about you.  In the case of this study, we are using your relative’s data for research purposes, and this is ‘a task in the public interest’. The University of Oxford, based in the United Kingdom is the data controller and is responsible for looking after your relative’s information and using it properly.

We will be using information from your relative’s medical records, in order to undertake this study. We will keep the minimum personally identifiable information about them indefinitely, for safety reasons, and because it is a valuable record.  This information will be held securely at the University of Oxford and the University of Edinburgh.

We will record your relative’s NHS/CHI number, date of birth and postcode to anonymously link results from the study to information held in electronic medical records at a population-wide level. These routine records are maintained by NHS Digital, and its successor NHSx. More information about how linking to routine health data as part of this study and what this means for your relative’s data can be found at [www.isaric4c.net/privacy](http://www.isaric4c.net/privacy).

This hospital will use *your relative’s name, NHS/CHI number and your contact details* to *contact you about the research study, and to oversee the quality of the study*. They will keep identifiable information about your relative from this study according to local policies. Further information about rights with respect to personal data is available at <https://compliance.web.ox.ac.uk/individual-rights> .

We will keep the minimum personally identifiable information about your relative indefinitely for safety reasons and because it is a valuable record of this outbreak event. There may be need to refer to this data for related very long-term follow up studies.

All information about your relative will be handled in confidence and only the people who were responsible for their care and for this study will know that your relative was a part of the study.

The data and samples collected during this study may be looked at by regulatory authorities, authorised individuals from University of Oxford, from the NHS Trust(s) or public health agencies.

**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?**

If you agree, we will do some genetic (DNA) tests on your relative’s samples to understand how their genes affected infections. The results of these tests would not have affected their medical care and we, regretfully, cannot tell you the results from these tests.

**Can I change my mind and withdraw my relative’s samples from the study in the future?**

Yes, you can withdraw your consent at any time without giving a reason.

**Where can I find more information?**

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/>

**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 relative’s 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.

NHS indemnity covers the clinical treatment with which your relative was provided.

The Patient Advisory Liaison Service (PALS) is a confidential NHS service in England which provides support for those who wish to make complaints or raise queries regarding the care your relative received 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: \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_**

**ISARIC/WHO Clinical Characterisation Protocol UK
INFORMED CONSENT FORM FOR BEREAVED RELATIVES**

30th August 2022. Version 10.2

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| ***IF YOU AGREE FOR YOUR RELATIVE’S SAMPLES AND INFORMATION TO BE USED IN THIS STUDY, PLEASE MARK YOUR INITIALS AGAINST THE STATEMENTS BELOW.*** |
| ***Statement:*** | ***Initials:*** |
| I agree to the use of my relative’s data in this research study. |  |
| I agree to the use of my relative’s samples, **including their DNA**, in this research study. |  |
| ***OR*** |
| I agree to the use of my relative’s samples, **but not their DNA**, in this research study. |  |
| ***Statement:*** | ***Initials:*** |
| I have read the summary information sheet dated 30th August 2022 version 10.2 (above) or it has been read to me. I understand the information and have no further questions about it. |  |
| I understand that participation is voluntary and that I am free to withdraw my relative’s samples from the study at any time, without giving any reason and without my rights being affected. |
| I give permission for my relative’s medical records and data 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 and my relative’s name 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. |
| ***Additional optional statements (if you do not agree to these statements, please leave your initials blank and tick ‘DO NOT AGREE’. Your relative’s samples will be used as above, but not in these extra aspects):*** | ***Initials:*** |
| I agree that my relative’s 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 my relative, 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 relative’s de-identified data and results of analyses, including the whole sequence of their DNA, can be shared with other scientists, including those in other countries.OR IF YOU DO NOT AGREE, TICK HERE ❑ |  |
| ***OR, IF YOU DO NOT AGREE FOR YOUR RELATIVE’S SAMPLES AND INFORMATION TO BE USED AT ALL, PLEASE INITIAL THE BOX BELOW.*** |
| ***Statement:*** | ***Initials:*** |
| **I do NOT agree to the use of my relative’s samples in this research study.** |  |

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

Date of consent: \_\_ \_\_ / \_\_ \_\_ \_\_ /\_\_ \_\_ \_\_ \_\_

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

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

Relationship to participant (e.g. wife/husband/child etc.):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of person giving consent: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Contact details of the participant’s representative:

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

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

E-mail \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Thank you for giving your permission for your relative’s samples to make a contribution to this global research activity.**

Please return this form to us by:

* Taking a clear photo of your consent form and sending it via Whatsapp (an encrypted messenger service to) **[\*\*\*CI/Deputy investigator study phone number\*\*\*]**

***Or***

* Taking a clear photo of your consent form and emailing it to red.cap@nhs.net (a secure NHS email account)

***Or***

* Posting in the envelope provided.

A relative, friend or carer could help you with taking the photo and sending it to us if you are unable to do this yourself.