**ISARIC/WHO Clinical Characterisation Protocol UK**

**SUMMARY** **CONSULTEE** **INFORMATION SHEET & DECLARATION FORM**

17th February 2020. Version 8.2

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

We are undertaking a research study involving people with infections due to emerging pathogens (new bugs). 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 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.

## What is this study about?

We need to find out more about how infections affect people. By studying the patient’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 patient, 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.

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 15mls (3 teaspoons) or less (depending on the patient’s weight).

All of these samples are voluntary. The patient or you as their consultee can them withdraw 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 patient will remain confidential. Their name and other personal details will not appear in any report, but we will share the results of analyses widely. The work we do with your 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.* For more information on how we process and protect data, please see the full information sheet.

## 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.

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?

Yes, you can withdraw them 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 patient’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 patient’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 patient 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 patient 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.**

**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 patient 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 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 is 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 care received as an NHS patient. However, PALS will not provide information specifically about this research study.

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

**Consultee Declaration Form**

17th February 2020. Version 8.2

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 summary information sheet dated 17th February 2020 (Version 8.2) or it has been read to me. I understand the information and have had the opportunity to ask questions about it. |  |
| I 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. |  |
| I understand that data and samples **including DNA from the participant will be used in this study.** |  |
| I 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. |  |
| **My advice is that the participant would be happy to participate in this research study.** |  |
| I understand that the participant’s **data and samples may be used for other unrelated ethically- approved research in the UK or elsewhere.**  Or if you think that the participant would not want this tick here ❑ |  |
| I 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 you think that the participant would not want this tick here ❑ |  |
| I 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 you think that the participant would not want this tick here ❑ |  |
| I understand that the participant may to be **contacted by the investigators to be invited to participate in future research studies.**  Or if you think that the participant would not want this tick here ❑ |  |

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

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

Relationship to participant: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

Person taking advice from consultee (PLEASE PRINT: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Research team member or health professional trained in taking consent for this study)

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

Contact details of participant

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

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Contact details of consultee

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

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**Witnessed Declaration:**

***If the consultee cannot read the form:*** I have no interest or involvement in this research study and I attest that the information concerning this research was accurately read and explained to the consultee in language they can understand, and that their advice on patient participation freely given.

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

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

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