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

**SUMMARY** **INFORMATION SHEET & CONSENT FORM FOR ADULT PATIENTS
- DATA AND SAMPLES INCLUDING SEMEN OR OTHER GENITAL SECRETIONS**

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

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

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 and exposures such as the one you recently had 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.

In addition to samples normally taken as part of your 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 you are coughing up mucus), urine and stool (faeces or ‘poo’). If specialist breathing support is required, we will take samples of lung fluid for analysis.

Video calls may be used to aid you in taking swabs if you wish. Digital photography may be used to characterise skin lesions and ensure swabs are taken from the same place or lesion.

We will take the same samples twice more over the next two weeks. We will also ask if you 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).

We ask men over the age of sixteen to provide semen samples and swabs from the meatal (urethral entrance at the tip of the penis). We ask women over the age of sixteen to provide vaginal swabs. These samples can be collected in privacy. Swabs can be self-administered. According to pathogen and nature of disease, the sampling schedule may be daily or reduced to a less frequent schedule e.g. day of expected discharge from hospital, 28d after discharge, or d1 of admission (recruitment), d3, d7, d14, d21 and then d28 after discharge, and any variation as is deemed acceptable by the participant. 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 anonymously 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 plan to keep the minimum personally identifiable information about you indefinitely for safety reasons and because it is a valuable record of this outbreak event and 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 my samples?**

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

With your permission, we will store your samples and use them for future ethically approved medical studies in the UK or elsewhere. We might use your 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 you, 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 your medical care. The main drawback to you of providing blood 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 your genes affect infections. The results of these tests won’t affect your medical care and we will not tell you the results from these tests.

**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. 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** 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, 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 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.

**ISARIC/WHO Clinical Characterisation Protocol
INFORMED CONSENT FORM FOR ADULT PATIENTS - DATA AND SAMPLES INCLUDING SEMEN OR OTHER GENITAL SECRETIONS**  30th August 2022. Version 10.2

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

|  |  |
| --- | --- |
| ***PLEASE MARK YOUR INITIALS AGAINST EACH STATEMENT TO WHICH YOU AGREE:*** |  |
| 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 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 **including my DNA.** |
| 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, including the whole sequence of my DNA, **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 ID: \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_**

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

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

Contact details of the participant:

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

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

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

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

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

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

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

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

**Witnessed Consent**
*If the consenting person cannot read the form or the completed form is contaminated and cannot be removed from the participant’s room:* 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: \_\_ \_\_ / \_\_ \_\_ \_\_ /\_\_ \_\_ \_\_ \_\_