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

**INFORMATION SHEET & CONSENT FORM FOR EXISTING SAMPLES**

17th August 2020. Version 1.0

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

We are running a study called ISARIC Clinical Characterisation Protocol UK (CCP-UK) and would like your permission to use your samples and information from your medical records in this research study. CCP-UK involves people who have or had an infection such as the one you 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 your permission to use your samples and medical records.

Once you have read it, if there is anything that is not clear, you can ask to speak to your local investigator by calling XXXX.

Agreement to being part of this study is completely voluntary and **will not** affect any future care or treatment you may have in any way.

**What is this study about?**

We need to find out more about how infections such as the one you had 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 agree for my samples to be used in this study?**

When you were in hospital you had samples taken to help the doctors looking after you better understand your illness and how to treat you. These samples were used to inform the care you received, but some of your 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 the samples to discover how people respond to infection, how treatments work and/or to develop new tests or treatments. You have the option to decide whether we can use blood samples to analyse your DNA and RNA. RNA, like DNA, carries genetic information. If you agree, we will examine your 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 samples to manufacture tests, treatments or other materials, including commercial products.

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

**What will happen to my information?**

All information about you will be kept confidential by those working on this study, and your 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.

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 data for research purposes, and this is ‘a task in the public interest’. The University of Oxford is the data controller and is responsible for looking after your information and using it properly.

We will be using information from your medical records, in order to undertake this study. We will keep the minimum personally identifiable information about you indefinitely, for safety reasons, and because it a valuable record.  This will be held securely at the University of Oxford, the University of Liverpool, Imperial College London and Public Health England. We will record your NHS 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 data can be found at [www.isaric4c.net/privacy](http://www.isaric4c.net/privacy).

Your hospital will use *your name, NHS 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 you from this study according to local policies.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at <https://compliance.web.ox.ac.uk/individual-rights> .

All information about you will be handled in confidence and only the people who are responsible for your care and for this study will know that you are 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 samples to understand how your genes affect infections. The results of these tests will not affect your medical care and, regretfully, we cannot tell you the results from these tests. To help keep your information confidential, your samples and any information recorded about you in this study will be ‘de-identified’ and assigned a study code. However, your DNA is unique to you so it can never be completely anonymous.

**What will happen if I don’t want to carry on with the study?**

You can withdraw your consent at any time without giving a reason. If when you choose to stop taking part in the study there are still some samples leftover that can be identified as yours, we can destroy them if you wish.

**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 **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 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 you were provided. 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: \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_**

**INFORMED CONSENT FORM FOR EXISTING SAMPLES**

17th August 2020. Version 1.0

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

|  |  |
| --- | --- |
| ***IF YOU AGREE FOR YOUR 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 data and samples, **including my DNA**, in this research study. |  |
| ***OR*** | |
| I agree to the use of my data and samples, **but not my DNA**, in this research study. |  |
| ***Statement:*** | ***Initials:*** |
| I have read the summary information sheet dated 17th August 2020 Version 1.0 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 from the study at any time, without giving any reason and without my rights being affected. |  |
| I give permission for my 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 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 DO NOT initial the boxes and tick ‘DO NOT AGREE’. Your samples will be used as above, but not in these extra aspects below):*** | ***Initials:*** |
| 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 ❑ |  |
| ***OR, IF YOU DO NOT AGREE FOR YOUR SAMPLES AND INFORMATION TO BE USED AT ALL, PLEASE INITIAL THE BOX BELOW.*** | |
| ***Statement:*** | ***Initials:*** |
| **I do NOT agree to the use of my samples in this research study.** |  |

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

Signature of participant: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_ \_\_ / \_\_ \_\_ \_\_ /\_\_ \_\_ \_\_ \_\_

**Thank you for giving your permission for your 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) 07958 335 337 ***or***
* Taking a clear photo of your consent form and emailing it to [red.cap@nhs.net](mailto:red.cap@nhs.net) (a secure NHS email account) ***or***
* Posting in the freepost 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.

Please keep a copy of this consent form for your records.