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

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

**FULL INFORMATION SHEET**

7th May 2020. Version 9.3

We are undertaking a research study involving people with infections such as the one you have recently acquired are of public health interest, which is why we have approached you.

You are invited to take part in this study but before you decide it is important for you to understand why the research is being done and what it would involve for you. 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 your care or treatment in any way.

**What is the study about?**

Infectious diseases affect millions of people around the world every year. Most cases are mild, but some people become very unwell. There is a great deal that we do not understand about existing infections, and new infectious diseases continue to appear. This research study will gain important information about your infection such as the one you have recently acquired so we can try to find better ways to manage and treat this infection in the future.

**What will happen if I take part in this study?**

We will collect information from your routine clinical records such as your signs and symptoms, medications that you are taking, and the results of any blood test and laboratory results that doctors have ordered in hospital. This will happen every day while you are in hospital.

If you agree, samples will be collected which are in addition to what would normally be collected for your medical care.

A blood sample will be taken shortly, together with a swab or suction sample from your mouth, nose and throat, a swab from any infected sites/sores, a sputum sample (if you are coughing up mucus), urine sample and a stool sample (or rectal swab if you are not passing stools).

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).

In a small number of people we will ask for an extra donation of blood of up to 240mls (about half a pint). This is about half as much blood as a normal donation to the blood transfusion service. A blood donation of this size is not expected to have any significant after-effects, and no lifestyle restrictions are required afterwards. This extra donation of blood could be used to study immune responses to infection, to develop, and set reference standards for, blood tests, and to make products, including commercial products.

In a small number of participants in special medical centres receiving advanced life support measures including circulation of blood through artificial lungs (extracorporeal membrane oxygenation), we will also obtain samples from within the breathing tubes and lungs using a standard technique with a thin, flexible instrument called a bronchoscope.

If any other samples are taken from you for regular care, and if there is leftover sample after the tests requested by your doctors are done, we will store the leftover to be tested.

**What will happen to the samples and 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 you and 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 of this outbreak event.  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. We will record your telephone number to contact you about follow-up samples and future studies. With your permission, we will contact you by letter, phone call or text message. 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).

This hospital will use *your name, NHS number and 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> .

We will use the blood samples to look at how the body fights the infection and how treatments given to you are working in your body. We will also use blood samples to analyse your DNA and RNA. 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.

All information about you will be handled in confidence and only the people responsible for your care and for this study will know that you were a part of the study. We will review your medical records and keep limited information about you on a secure file. All information and samples will be labelled only with a number so that they cannot be directly linked to you personally.

With your permission, we would also like to store your samples and use them for future ethically approved medical research. We might use your samples to manufacture tests, treatments or other materials, including commercial products.

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.

**Are there any benefits to taking part in this study?**

There is no benefit to you personally. The information gained from this study may not be available in time to affect your care. Any results available while you are in hospital will be given to your treating doctor. The information we learn may help in caring for other patients in the future.

**What are the risks of being in the study?**

If you take part in the study and only clinical data is collected from the routine medical records there is minimum risk, all information will be used anonymously (no one will know that this information relates to you).

If you agree to collect samples, being a part of this study means that more samples will be taken than are needed for normal care. Whenever possible these samples will be taken at the same time as regular samples to reduce the extra procedures. There is a risk of pain or discomfort when samples are taken.

Bronchoscopy will only be performed in specialist centres with lots of experience of the technique. This will only be done if your blood is receiving oxygen from artificial lungs so there is no risk of impaired oxygen delivery. There is a less than 1% risk of accidental lung puncture during this process.

We are doing DNA and RNA (genetic) tests, to understand their influence on the disease caused by this infection. The results of these investigations are unlikely to have any implications for your future care. For these reasons we would not attempt to identify you or inform you of any results from DNA and RNA testing.

**Who is responsible and what if something goes wrong?**

The research is organised by the University of Oxford with the support of collaborators at this hospital, none of who will benefit financially from the study. It has been reviewed and given a favourable opinion by **Oxford C Research Ethics Committee (Ref 13/SC/0149)**.

The University of Oxford has arrangements in place to provide for harm arising from participation in the study for which the University is the Research Sponsor. NHS indemnity operates in respect of the clinical treatment with which you are provided.

**If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of 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)**.**

The Patient Advisory Liaison Service (PALS) is a confidential NHS service it can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. PALS is unable to provide information about this research study.

**Can I request that I be withdrawn from the study at any point?**

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 anytime you request it.

**What about future research?**

With your consent, we would like to keep your contact details after your participation in this study is complete, so we may inform you of opportunities to participate in future, research. This is entirely optional and agreeing to be contacted also does not oblige you to take part in any future research.

Your contact details would be stored electronically on a secure server and only authorised individuals at **[\*\*\*hospital\*\*\*]** will have access to it. You can ask us to have your contact details removed from our database at any time.

**What if I would like further information about the study?**

If you would like more information about the study you can contact the Local Investigator in your hospital **[\*\*\*local\_investigator\_name\*\*\*]** or telephone the Local Research office on **[\*\*\*local\_research\_office\_phone\_number\*\*\*].**