  **[\*\*\*Hospital logo\*\*\*]**

Local lead investigator: **[\*\*\*Local\_Lead \*\*\*]**

**ISARIC/WHO Clinical Characterisation Protocol**

**FULL CONSULTEE INFORMATION SHEET**

17th February 2020. Version 8.2

We are undertaking a research study involving people with infections due to emerging pathogen. 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 opinion whether or not he/she could 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 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 their infection so we can try to find better ways to manage and treat this infection in the future.

**What will happen if the patient takes part in this study?**

We will first collect information from the participant routine clinical records such as participant’s signs and symptoms, medications that he/she is taking, and the results of any blood test and laboratory results that doctors have ordered when hospitalise. This will happen every day while the participant is in hospital.

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

A blood sample might be taken now together with a swab or suction sample from the participant's mouth, nose and throat, a swab from any infected sites/sores, a sputum sample (if they are coughing up mucus), urine sample and a stool sample (or rectal swab if they 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 15mls (3 teaspoons) or less (depending on the patient’s weight).

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

**What will happen to the information and samples?**

All information about the participant will be kept confidential by those working on this study, the participant’s name or other information 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 severe acute respiratory infection.

Data protection regulation requires that we state the legal basis for processing information about the participant.  In the case of research, this is ‘a task in the public interest’. The University of Oxford is the data controller and is responsible for looking after the participant’s information and using it properly.

We will be using information from the participant and their 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 a valuable record of this outbreak event.  This will be held securely at the University of Oxford and the University of Liverpool.

This hospital will use their name, NHS number and contact details to contact them about the research study, and to oversee the quality of the study. They will keep identifiable information about them from this study according to local policies.

Data protection regulation provides the participant or you as their consultee with control over your personal data and how it is used. When you as their consultee agree to their 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 the participant work in the body. We will also use the blood sample to analyse the participant's DNA and RNA. We will examine the participant's 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 the participant will be handled in confidence and only the people responsible for the participant's care and for this study will know that the participant were a part of the study. We will review the participant's medical records and keep limited information about the participant on a secure file. All information and samples will be labelled only with a number so that they cannot be directly linked to the participant.

We will store the participant's samples and use them for future ethically approved medical research. We may use the 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.

The participant’s GP will be informed of they are taking part in this study.

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

There is no benefit to the participant personally. The information gained from this study may not be available in time to affect the participant's care. Any results available while the participant is 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 the participant takes 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 belonged to the participant).

If agreed to collect samples, being 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.

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 their future care. For these reasons we would not attempt to identify them or inform them 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 or the participant have been approached or treated, or how your information is handled during the course of this study, you should contact **[\*\*\* Local Investigator\*\*\*] [\*\*\*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 or the participant with support for any complaints or queries you may have regarding the care the participant receives as an NHS patient. PALS is unable to provide information about this research study.

**Can I request that my declaration or the participant be withdrawn from the study at any point?**

Yes, you or the participant can withdraw at any time without giving a reason and without affecting the participant's care. Any samples that have not already been analysed can be destroyed anytime you or the participant request it.

**What about future research?**

If you believe that the participant would not object to this,, we would like to inform the participant of opportunities to participate in future, research.

This is entirely optional and agreeing to be contacted also does not oblige them to take part in any future research.

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

**What if I have any problems or would like further information about the study?**

If you would like more information about the study you can contact the Local Lead Investigator in your hospital **[\*\*\*local\_lead\*\*\*]** or telephone the Local Research office on **[\*\*\*phone\_number\*\*\*].**