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

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

**FULL INFORMATION SHEET FOR THE PROXY OF AN ADULT WITH INCAPACITY (THEIR GUARDIAN, WELFARE ATTORNEY OR CLOSEST FAMILY MEMBER) IN SCOTLAND AND THE CONSULTEE OF AN ADULT WITHOUT MENTAL CAPACITY IN REST OF UK
DATA AND SAMPLES**

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

We are undertaking a research study involving people with infection due to or exposure to an emerging pathogen (“bug”), chemical, toxin or potentially harmful energy source of public health interest. We are asking you about the participation of an individual who is not able to consent for themselves, because they lack the legal mental capacity to do so. To help decide if they should join the study, we would like to ask your view on whether or not you consider they 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. When deciding, please put aside your own feelings and wishes and consider what the past and present feelings and wishes of the person you are representing would have been, had they been able to consent for themselves.

**What is the study about?**

Infectious diseases and hazardous exposures 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, hazardous exposures, 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 participant 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 they are 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). 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 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 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 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.

UK Data protection regulation requires that we state the legal basis for processing information about the participant.  In the case of this study, we are using the participant’s data for research purposes, and this is ‘a task in the public interest’. The University of Oxford, based in the United Kingdom 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 Edinburgh. We will record the participant’s NHS number (in Scotland the Community Health Index), 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 in England and in Scotland by NHS Scotland, Public Health Scotland, and National Records of Scotland. We will record the participant’s telephone number to contact them about follow-up samples and future studies. With permission, we will contact the participant 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 the participant’s data can be found at [www.isaric4c.net/privacy](http://www.isaric4c.net/privacy).

This hospital will use their name, NHS/CHI 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.

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. There may be need to refer to this information for related very long-term follow up studies.

UK Data protection regulation provides the participant or you as their proxy/consultee with control over the participant’s personal data and how it is used. When you as their proxy/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 but there will not be any financial reward if samples are used for any of these purposes.

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 not be informed that 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.

Bronchoscopy will only be performed in specialist centres with lots of experience of the technique. This will only be done if their 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 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)** and **Scotland A Research Ethics Committee (Ref 20/SS/0028).**

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 Research Governance, Ethics & Assurance (RGEA) office on 01865 616480, or the director of RGEA, email ctrg@admin.ox.ac.uk.

The Patient Advisory Liaison Service (PALS) is a confidential NHS service in England and Wales. 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.

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.

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

The participant or you as their proxy/consultee 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\*\*\*].**