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

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

**FULL ADULT INFORMATION SHEET - DATA ONLY**

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 such as the one you have recently experienced.

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 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 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.

**What will happen to the 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.

UK 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, based in the United Kingdom 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 and the University of Edinburgh. We will record your NHS number (in Scotland your 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 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/CHI 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.

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. We will review the need to retain your data ever five years. There may be need to refer to your data for related very long-term follow up studies.

UK 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 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.

The data 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.

Your GP will not be informed that you are taking part in this study.

**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).

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

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

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 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\*\*\*].**