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

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

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

**FULL INFORMATION SHEET FOR PARENTS/GUARDIANS OF CHILD OR YOUNG PERSON UNDER 16years- 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, which is why we have approached you.

We are asking you about the participation of a child or young person who is below the legal age at which they can consent to participate in research. We are approaching you because we understand that you are the parent or legal guardian of such a child or young person (hereafter referred to as your child). Please declare now if you are not the parent or legal guardian of this child.

Where possible, we will also give your child the opportunity to express his/her views and assent to participate.

Before you decide about your child being involved in this research it is important for you to understand why the research is being done and what it would involve for your child. 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 child's care or treatment in any way.

**What is the study about?**

Infectious diseases and exposure of public health concern affect millions of people around the world every year. This research study will gain important information about your child’s infection or exposure so we can try to find better ways to manage and treat these conditions in the future.

**What will happen if my child takes part in this study?**

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

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

A blood sample might be taken now together with a swab or suction sample from his/her 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 15mls (3 teaspoons) or less (depending on the participant’s weight).

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

**What will happen to my child’s information and samples?**

All information about your child will be kept confidential by those working on this study, and your child’s 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 child’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 your information and using it properly.

We will be using information from your child and your child’s medical records, in order to undertake this study. We will keep the minimum personally identifiable information about your child 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 child’s 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 that you and your child may wish to participate in. With your permission, we will contact you by letter, phone call or text message.

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.

More information about how linking to routine health data as part of this study and what this means for your child’s 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.

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> .

We will use the blood samples to look at how the body fights the infection or responds to exposures and how treatments given to your child work in their body. We will also use the blood sample to analyse your child's DNA and RNA (which carries important information about viruses). We will examine your child'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 your child will be handled in confidence and only the people responsible for your child’s care and for this study will know that he or she was a part of the study. We will review your child’s medical records and keep limited information about your child on a secure file.

All information and samples will be labelled only with a number so that they cannot be directly linked to your child.

With your permission, we would also like to store your child’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 child’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 you or to your child. The information gained from this study may not be available in time to affect your child’s care. Any results available while your child is in hospital will be given to his or her 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?**

Being a part of this study means that if your child takes part in the study and only clinical data is collected from the routine medical records there is a minimum risk, all information will be used anonymously (no one will know that this belonged to your child).

If you 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 small risk of pain or discomfort when samples are taken.

We are going 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 will not attempt to identify your child or inform your child 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 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 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 my child be withdrawn from the study at any point?**

Yes, you can withdraw your child at any time without giving a reason and without affecting your child’s care. Any samples that have not already been analysed can be destroyed anytime if you or your child 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 Lead Investigator in your hospital **[\*\*\*local\_lead\*\*\*]** or telephone the Local Research office on **[\*\*\*phone\_number\*\*\*].**