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

**SUMMARY INFORMATION SHEET & CONSENT FORM FOR PARENTS/GUARDIANS -SAMPLES AND DATA FROM CHILDREN UNDER 16 YEARS OLD**

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

We are undertaking a research study involving people with infections or exposures to emerging pathogens (new bugs), harmful toxins, chemicals, and energy sources. We are asking you about the participation of a child or young person who is below the 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. This information is being given to you to explain why the study is being done, what it involves and why we would like your child to take part.

Once you have read it, one of our team will go through the information with you. Please ask us if there is anything that is not clear. Your agreement to be part of the study is completely voluntary and **will not** affect your child’s care or treatment in any way.

## What is this study about?

We need to find out more about how infections and exposures such as the one your child recently had affect people. By studying your child, we hope to find better ways to diagnose and manage people with this and similar conditions.

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

We will collect information about your child, including any other medical problems they may have, any medicines they take, the treatments they receive and the results of tests they have.

In addition to samples normally taken as part of their medical care, other samples will be collected as well. This will include blood, mouth, nose or throat swabs or suction samples, swabs from any infected site, a sputum sample (if they are coughing up mucus), urine and stool (faeces or ‘poo’). Additional blood samples would be calculated to be safe for their size.

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.

All of these samples are voluntary. Your child or you as their parent can withdraw them from the study at any time, and don’t need to give a reason for this.

## What will happen to my child’s information?

All information about your child will remain confidential. Their name and other personal details will not appear in any report, but we will share the results of analyses widely.

We will record your child’s NHS/CHI number, date of birth and postcode (to anonymously link study results to information in electronic medical records) and your telephone number (to arrange follow-up samples). With your permission, we will contact you by letter, phone call or text message.

The work we do with your child’s data is ‘a task in the public interest’. The way their data is used is carefully regulated by UK law. *We will keep the minimum personally identifiable information about your child indefinitely for safety reasons, because it is a valuable record of this outbreak event, and for future very long-term follow-up studies.*

For more information on how we process and protect data, please see the full information sheet or visit [www.isaric4c.net/privacy](http://www.isaric4c.net/privacy).

## What will happen to their samples?

We will use the samples to discover how your child responds to infection, how treatments work and to develop new tests or treatments. As part of this, we will analyse their genetic information (DNA) to discover why people respond differently to infections.

We will store your child’s samples and use them for future ethically approved medical studies in the UK or elsewhere. We might use their samples to manufacture tests, treatments or other materials, including commercial products.

## What are the benefits to taking part in this study?

There is no direct benefit to participants, but the research may help others.

## What are the risks?

There is a small risk from taking the samples. Whenever possible, the samples will be taken at the same time as samples necessary for their medical care. The main drawback of donating samples is the slight discomfort or pain when samples are taken.

We are doing genetic (DNA) tests to understand how genes affect infections. The results of these tests won’t affect your child’s medical care and we will not tell them the results from these tests.

## Can I request that my child be withdrawn from the study?

Yes, you or they can withdraw them at any time without giving a reason and without affecting their care. Any samples that have not already been analysed can be destroyed, if you request this.

## Will the samples be used for future research?

We would like to keep your contact details after the study is complete so we may ask if you are willing for your child to participate in future studies. This is entirely optional. Your contact details would be stored electronically on a secure computer system. You or your child can ask us to have these contact details removed from our database at any time.

## Where can I find more information?

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

If you would like to know about the progress of the study or if the results of the study, you can visit our website for participants at <http://isaric.net/ccp/uk/info/>

## Who is legally responsible for this study?

All UK research needs a ‘Research Sponsor’, which in this case is the University of Oxford. The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that your child suffers any harm as a direct consequence of their participation in this study. NHS indemnity operates in respect of the clinical treatment which is provided.

The data and materials related to this study may be inspected by regulatory authorities, including the Research Sponsor, NHS Trust(s) or public health agencies in the UK. This study has been reviewed and given a favourable opinion by the **Oxford C NHS Research Ethics Committee – reference number: 13/SC/0149** and **Scotland A Research Ethics Committee (Ref 20/SS/0028).**

## Who do I complain to if I am unhappy about any part of this research study?

If you wish to complain about the way in which you or your child have been approached, treated, or how information is handled for 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).

NHS indemnity covers the clinical treatment with which is provided. The Patient Advisory Liaison Service (PALS) is a confidential NHS service which provides support for those who wish to make complaints or raise queries regarding care received as an NHS patient. However, PALS will not provide information specifically 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.

PARTICIPANT ID: \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_

**ISARIC/WHO Clinical Characterisation Protocol UK   
CONSENT FORM FOR PARENTS/GUARDIANS -SAMPLES AND DATA OF ALL CHILDREN UNDER 16 YEARS OLD** 30th August 2022. Version 10.2

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| --- | --- |
| PLEASE MARK YOUR INITIALS AGAINST EACH STATEMENT TO WHICH YOU AGREE: | |
| I have read the summary information sheet dated 30th August 2022 version 10.2 (above) or it has been read to me. I understand the information and have had the opportunity to ask questions about it |  |
| I understand that his/her participation is voluntary and that I am free to withdraw him/her from the study at any time, without giving any reason and without his/her medical care or rights being affected. |
| I agree that data and samples including DNA from my child can be used in this study. |
| I agree for my child’s medical records and data collected during the study to be examined by the Research Sponsor (the University of Oxford), by regulatory authorities, representatives of the NHS Trust(s) or public health agencies who oversee this research. |
| I agree that a copy of this consent form which will include my name, address and phone number will be sent to the central study team (where it will be kept in a secure location), to allow confirmation that my consent was given and for administration of the study. |
| **I agree for my child to participate in this research study.** |
| I agree that my child’s data and samples may be used for other unrelated ethically approved research in the UK or elsewhere.  Or if you do not agree to this tick here ❑ |  |
| I agree that samples taken from my child, or materials or data derived from those samples, may be used to manufacture tests, treatments or other products, including commercial products and understand that there will not be any financial reward if samples are used for any of these purposes.  Or if you do not agree to this tick here ❑ |  |
| I agree for de-identified data and results of analyses, including the whole sequence of my child’s DNA, to be shared with other scientists, including those in other countries. Or if you do not agree to this tick here ❑ |  |
| I agree to be contacted by the investigators if they wish to invite my child to participate in future work, including research studies.  Or if you do not agree to this tick here ❑ |  |

PARTICIPANT ID: \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_

Name of child or young person (PLEASE PRINT):

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Name of parent/legal guardian/person with parental authority: (PLEASE PRINT):

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Relationship to child or young person: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Contact details of participant’s parent/legal guardian/person with parental authority:

Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Phone number \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_

Email of parent/legal guardian/person with parental authority: (PLEASE PRINT):

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Thank you for your contribution to this important global research activity.**

Person taking consent: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Research team member or health professional trained in taking consent for this study)

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_ \_\_ / \_\_ \_\_ \_\_ /\_\_ \_\_ \_\_ \_\_

PARTICIPANT ID: \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_

**Witness Declaration**

***If the parent/guardian/person with parental authority cannot read the form or the completed form is contaminated and cannot be removed from the participant’s room:*** I have no interest or involvement in this research study. I have been introduced to the participant’s parent/guardian/person with parental authority and identified as a witness to their consent. I attest that the information concerning this research was accurately read and explained to the parent or person with parental authority in their first language, that they have understood, and that the declaration was freely given by the parent or person with parental authority.

Name of witness (PLEASE PRINT): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_ \_\_ / \_\_ \_\_ \_\_ /\_\_ \_\_ \_\_ \_\_

**ASSENT OF COMPETENT YOUNG PEOPLE**

Consistent with best practice, and when appropriate, children and young people should be invited to indicate they are willing to participate in this study (assent). Should a competent young person decline to being involved, our study protocol is that the young person’s decision should be respected.

Where a child or young person is unable to express their wishes for reasons of acute illness (or otherwise), their views should be sought and recorded at the earliest opportunity once recovered. **Separate assent forms are available for young children (age <12 years) and young people (age 12 to 16 years).**