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

**EXTRA SAMPLING OF CONVALESCENT PATIENTS** - **INFORMATION SHEET & CONSENT FORM FOR PARENTS/GUARDIANS OF CHILDREN UNDER 16 YEARS**

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

You are being asked about your child taking part in an extra part of this research study involving people who have recovered from an infection or exposure of public health interest.

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.

**What is this study about?**

This form is for parents/guardians who have already consented for a child or young person to participate in the ISARIC/WHO Clinical Characterisation Protocol and who have recovered from their illness or exposure.

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

We would use a needle to obtain a single extra donation of blood. The amount of blood we would take will be calculated based on your child’s weight, at 2.4ml/kg, that is less than half a teaspoon per kilogram, and is considered safe by independent experts in child health.

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

This extra donation of blood could be used to study immune responses to infection, to develop tests, and set reference standards for blood tests, and to make products, including commercial products.

**What are the benefits to my child taking part in this part of the study?**

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

**What are the risks?**

A blood donation of this size is not expected to have any significant after-effects, and no lifestyle restrictions are required afterwards.

**Can I request that my child be withdrawn from the study?**

Yes, you can withdraw your child 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 wish.

**Will the samples be used for future research?**

With your consent, we would like to keep your contact details after the study is complete so we may ask if your child is willing to participate in future studies. This is entirely optional.

Your contact details would be stored electronically on a secure computer system separately from the study data. You can ask us to have your 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 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/>

There may be opportunities to attend events relating to the study or to join a panel of research participants who can make further contributions to this research and future research studies. We will post information about any such events on the participants’ website.

**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 you suffer any harm as a direct consequence of your participation in this study.

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 your 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.

NHS indemnity covers the clinical treatment with which you are 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 the care you receive 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**

**EXTRA SAMPLING OF CONVALESCENT PATIENTS UNDER 16 YEARS -** **PARENT/GUARDIAN CONSENT FORM**

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 Parent/Guardian information sheet for Extra Sampling of Convalescent Patients 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 my child’s 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 give permission 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 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 to the use of my child’s data and samples **including their DNA.** |  |
| 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, TICK HERE ❑ |  |
| I agree that samples taken from my child, or materials or data derived from those samples, can be used to **manufacture tests, treatments or other products, including commercial products.** OR IF YOU DO NOT AGREE, TICK HERE ❑ |  |
| I agree that my child’s de-identified data and results of analyses, including the whole sequence of my child’s DNA, **can be shared with other scientists, including those in other countries**.OR IF YOU DO NOT AGREE, 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, 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: \_\_ \_\_ / \_\_ \_\_ \_\_ /\_\_ \_\_ \_\_ \_\_

**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 specifically for extra convalescent sampling are available for young children (age <12 years) and young people (age 12 to 16 years).**