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

**ISARIC/WHO Clinical Characterisation Protocol for Severe Emerging Infections  
IRAS Ref. 126600**

**INFORMATION SHEET FOR CHILDREN YOUNGER THAN 12 YEARS OLD**

Parents/guardians/carers are asked to go through this information with their child. Please consider using the cartoon sheet to help explain the study to young children.

**Please ask study staff if you or your child has any questions.**

We want to find out why and how with an infection such as you have gotten is making you unwell so that we can help other children like you.

**What does this mean for me?**

To help us finding out more about what is making you and other children unwell we will collect information from your medical records when you are in hospital.

In addition we will take some extra samples of blood and other body tissue while you are in hospital.

These are extra to what would normally be collected for your care. Each time we will take:

* a small blood sample
* a mouth, nose and throat sample (a wipe with a cotton bud or small sponge)
* a swab from any sore skin
* a bit of sputum (chest spit / phlegm) sample
* a small urine sample (wee)
* a small stool sample (poo) or rectal (bottom) swab.

The amount of blood will depend on how big you are. We will weigh you so that we only take a safe amount. We will explain how much blood will be taken at each visit. We will also keep any leftover samples from your normal care. We will make sure the amount of blood is as small as possible.

We will take the same samples twice more during your illness. When you are better we will ask you to come back to the hospital give us a further set of samples.

**Do I have to take part?**

It is up to you and your parents to decide if you would like to take part in helping us.

If you don’t want to take part, then you don’t have to.

Either way, your decision will not affect your care and treatments in any way.

**What will happen to the information and samples?**

All information about you will be kept private. Only the people responsible for your care and for this study will know that you were involved in this study.

If you agree for us to take samples, we will use the samples to see how your body fights the infection and how well medicines given to you work to make you better. All information about you will be kept private.

**Are there any benefits to taking part in this study?**

No. By helping us find out more about why you are ill, we will be able to help look after children better in the future. In addition to the data we collect, if samples are taken, being a part of this study means that more samples will be taken than are needed for normal care.

**Who has reviewed this study?**

This study has been reviewed by the **Oxford C NHS Research Ethics Committee – reference number: 13/SC/0149** and they are happy for this study to take place.

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

**YOUNG CHILD (<12 YEARS OLD) ASSENT FORM**

**ISARIC/WHO Clinical Characterisation Protocol**

Please tick the boxes if you agree. If you don’t agree, leave the boxes empty.

|  |  |
| --- | --- |
| I have been told about the study and given the information sheet about it and have had the chance to ask questions. |  |
| I know I don’t have to take part. If I do, I can change my mind – the doctors and nurses will still look after me. |  |
| I do not mind if someone doing the research looks at my medical records and collects my information - I know the people doing the study will keep personal things about me private. |  |
| I understand samples for the study may be collected from me when I am in hospital. |  |
| I agree to take part |  |

Name of Young Participant (PLEASE PRINT): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Legal Guardian/Carer (PLEASE PRINT):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Relationship: \_­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: \_\_ \_\_ / \_\_ \_\_ \_\_ /\_\_ \_\_ \_\_ \_\_

Name of Person taking assent (PLEASE PRINT): \_\_\_\_\_\_­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

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

**Witnessed Assent**  
*If the assenting person 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 and identified as a witness to their assent. I attest that the information concerning this research was accurately read and explained to the participant in language they can understand. I attest that assent was freely given by the participant.

Witness name (PLEASE PRINT): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of witness: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_ \_\_ / \_\_ \_\_ \_\_ /\_\_ \_\_ \_\_ \_\_

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