PARTICIPANT ID : I__I I__I I__I I__I I__I -- I__I I__I I__I I__I

ISARIC/WHO Clinical Characterisation Protocol for Severe Emerging Infections (COVID-19)

INFORMATION SHEET FOR CHILDREN YOUNGER THAN 12 YEARS OLD

1st February 2020. Version 3.1

Principal Investigator	
Organisation	
Contact details for Principal Investigator	
Study Approval	
NHSRC contact details	

Parents/guardians/carers are asked to go through this information with their child and the research team. 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 a problem with your chest 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 may take some extra samples of blood and other samples 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 from your vein or your finger
- one throat swab (a wipe with a cotton bud) from your throat
- 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 weight 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 every other day for two weeks, and then every week for as long as you are unwell. When you are better will ask you to come back to the hospital or clinic in 3 and 6 months time to give us one more blood sample.

Do I have to take part?

It is up to you and your parents to decide if you should 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 in your chest 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.

Can I request that I stop being in the study at any point?

Yes, you or your parent can stop at any time without giving a reason. This won't affect the way doctors treat you. If you want us to destroy the information and samples we have collected we can do this at your or your parent's request.

PARTICIPANT ID : I__I I__I I__I I__I I__I -- I__I I__I I__I I__I

YOUNG CHILD (<12 YEARS OLD) ASSENT FORM

ISARIC/WHO Clinical Characterisation Protocol for Severe Emerging Infections (COVID-19)

Please respond to the following statements by putting your initials or your thumbprint in the spaces provide ~~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 patient: _____ Date: _____

Signature: _____

OR

Thumbprint if patient cannot write:

PARTICIPANT ID : I__I I__I I__I I__I I__I -- I__I I__I I__I I__I

Name of guardian/carer: _____ Date: _____

–Signature: _____

OR

Thumbprint if patient cannot write:

Witnessed Consent

If the consenting party cannot read the form: I have no interest or involvement in this research study and I attest that the information concerning this research was accurately read and explained to the patient in language they can understand, and that informed consent was freely given by the patient

Witness name: _____

Signature: _____ Date: _____

Name of person taking consent: _____

Date: _____ Signature: _____

Thank you for your help with this important research.