PARTICIPANT ID : I__I 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 YOUNG PEOPLE AGE 12 TO 176 YEARS OLD

1st February 2020. Version 3.1

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

Introduction

We are undertaking a research study involving people with severe new chest infections due to emerging pathogens of public health concern. We have come you to ask if you would be willing to help us because you have a chest infection.

Before deciding if you want to be involved, it is important for you to understand why this research is being done and what it would involve for you. 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

What is the study about?

- Infectious diseases affect millions of people around the world every year.
- New infections appear. Most cases are mild, but some people become very unwell.
- There is a lot that we do not understand about these new infections.
- By understanding why young people like you are unwell we can try to find better ways to manage and treat people in the future.

Do I have to take part?

- It is up to you and your parents/guardians/carer to decide if you should be involved in helping us.
- If you don't want to be involved, then you don't have to.

- Either way, your decision will not affect your care and treatments in any way.
- **The choice is yours.**

What will happen if I take part in this study?

We will collect information from your clinical records when you are in hospital, including medication taken and laboratory results. We may collect samples that are extra to what would normally be collected for your normal care in hospital. If samples are taken, each time we will take:

- a blood sample
- a 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 urine sample (wee)
- a stool sample (poo) or rectal (bottom) swab.

The amount of blood will be small and will depend on your weight so that we only take a safe amount. The study staff can tell you how much blood will be taken at each visit. If we cannot take blood from a vein, we may take blood from a finger or heel prick.

Whenever possible these samples will be taken at the same time as regular samples to reduce the extra procedures.

We will take the same samples every other day for two weeks and then every week for as long as you are unwell up to a maximum of 100 days.

If there are any leftovers from other samples taken (for example CSF) for your regular care, we will store these leftovers for this research.

When you have recovered we will also ask you to return to the hospital or clinic in 3 months and 6 months to have a blood sample taken.

What will happen to my information?

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

If you agree, we will also store your data and use it for future approved related medical research. The data collected during this study at any time may be seen and shared with public health agencies.

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What will happen to my samples?

We will use your blood samples to look at how your body fights the infection and how the treatment given works in your body. Whilst we current do not have capacity to do so, we may , in future ~~We will~~ also examine your DNA and RNA together with the DNA and RNA from many other people to try to find out what makes some people more likely to get severe infection. Some of the tests may be done in different countries. DNA contains the genetic information passed on from parents to their children. DNA acts like a recipe holding the instructions telling our bodies how to develop and function. RNA is a copy of DNA naturally made by the body.

If you agree, we will also keep samples (for example CSF) for possible future use in other related medical research. This will only be done as a properly approved study. The samples collected during this study may be seen and shared with public health agencies.

Are there any benefits to taking part in this study?

There are no benefits for you personally. By helping us find out more about why you are ill, we will be able to help look after young people better in the future.

What are the risks of being in the study?

If only clinical data is collected there is a minimum risk, all information will be used anonymously (no one will know your name). If samples are taken, there is a small risk of pain or discomfort when samples are taken.

Can I request that I be withdrawn from the study at any point?

Yes, you or your parent can withdraw at any time without giving a reason and without affecting the participant's care. Any samples that have not already been analysed can be destroyed anytime you or the participant request it.

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Local lead investigator:

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ASSENT OF COMPETENT YOUNG PEOPLE (COVID-19)

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Consistent with best practice, 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

Please respond to the following statements by putting your initials or your thumbprint in the spaces provided ~~Please tick the box if you agree~~	
I have read the leaflet about the study and understand it.	
I know I do not have to take part if I don't want to and can change my mind. The doctors and nurses will still look after me	
I do not mind if someone doing research looks at my medical records to see if the study is done in the right way. I know the people who are going the research will keep personal things about me private	
I agree to take part in the study and to share information from my medical records.	
I agree to take part in the study and to give samples to the study	
I agree to let someone talk to me about ~~an~~other studies~~y~~ in the future to see if I wish to take part in these~~, at this study ends~~. OR IF YOU DO NOT AGREE, TICK HERE ❑	

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Name of patient: _____ Date: _____ Signature: _____

OR

Thumbprint if patient cannot write:

Name of guardian/carer: _____ Date: _____ Signature: _____

OR

Thumbprint if guardian 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: _____

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Name of person taking consent: _____ ~~Date:~~ _____

Signature: _____ Date: _____