Local lead investigators:

Clinical characterization and preparedness for COVID-19 disease

INFORMATION SHEET FOR YOUNG PEOPLE AGE 12 TO 17 YEARS OLD

We are undertaking a research study involving people with the current corona virus infection causing COVID-19 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.
- Currently there is an outbreak of COVID-19 pandemic in [state your country] and you have the infection
- There is a lot that we do not understand about this new infection.
- 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/career 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.

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 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.

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. We will also examine your Genetic material together with the Genetic material 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.

If you agree, we will also keep samples 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 (non-study staff will not know your name). If samples are taken, there is a small risk of pain or discomfort when samples are taken.

Cost to patients and compensation for participants

Your participation in this study is not linked to any financial transaction involving you in any direction. Funding for this study is severely limited under this crisis situation. In addition, the majority of the sampling done will be for routine clinical care upon which the research will ride. The current situation is that of an emergency, where it is actually a necessity in the national interest that research of this nature is conducted. Given the present lack of funding, we are simply unable to offer any compensation. However, should funds become available for the research, we shall seek you out and duly compensate you.

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ASSENT OF COMPETENT YOUNG PEOPLE

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

	Agree	Disagree
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 another study in the future, at this study ends. OR IF YOU DO NOT AGREE, TICK HERE ❑		

Name of patient: _____ Date: _____ Signature: _____

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

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