

Local lead investigators:

Clinical characterization and preparedness for COVID-19 disease

INFORMATION SHEET FOR ADULT PATIENT

We are undertaking a research study involving people with the current corona virus infection causing COVID-19 due to emerging pathogens of public health interest, which is why we have approached you.

You are invited to take part in this study but before you decide it is important for you to understand why the research is being done and what it would involve for you. Please take time to read this information carefully. 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 and time to decide. Your decision is completely voluntary. The decision you make **will not** affect your care or treatment in any way.

What is the study about?

Infectious diseases affect millions of people around the world every year. Most cases are mild, but some people become very unwell. There is a great deal that we do not understand about existing infections, and new infectious diseases continue to appear. Currently there is an outbreak of COVID-19 pandemic in [state your country here] and your child has the infection. This research study will gain important information about your respiratory infection so we can try to find better ways to manage and treat this infection in the future.

What will happen if I take part in this study?

After your consent to participate, we will take information about your background. In addition to this, we will collect information from your hospital records that your doctor has written or received from all healthcare givers and people who support him/her in making his/her diagnosis including results from laboratory tests. This will happen every day while you are in hospital.

If you agree, samples will be collected which are in addition to what would normally be collected for your medical care.

A blood sample might be taken now, together with a swab or suction sample from your nose and throat, a swab from any infected sites/sores, a sputum sample (if you are coughing up mucus), urine sample and a stool sample (or rectal swab if you are not passing stools).

We will take the same samples again over the next eleven days, every second day, and then every week for as long as you are unwell up to a maximum of 100 days. We will also invite you to return to the hospital or clinic in 3 months and 6 months to have a blood sample taken. Each blood sample will take 15mls (3 teaspoons) or less (depending on your weight).

If any other samples are taken from you for regular care, and if there is leftover sample after the tests requested by your doctors are done, we will store the leftover to be used for further laboratory tests.

What will happen to the samples and information?

All information about you will be kept confidential by those working on this study, and your name or other identifiers will not be used in any reports about this study. The results of the study will be shared as quickly as possible with health authorities, and doctors to help them treat patients with the current corona virus infection which is called COVID-19. Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest'. [state your institution here] are the data controller and is responsible for looking after your information and using it properly.

We will be using information from you and your medical records, in order to undertake this study. We will keep the minimum personally identifiable information about you indefinitely for safety reasons and because it a valuable record of this outbreak event. This will be held securely by the scientists running this study under the control of the [state your institution here].

This hospital will use your name and contact details to contact you about the research study, and to oversee the quality of the study. They will keep identifiable information about you from this study according to local policies.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, some of those rights may be limited in order for the research to be reliable and accurate.

We will use the blood samples to look at how the body fights the infection and how treatments given to you are working in your body. We will also use blood samples to analyse your Genetic material. We will examine your Genetic material together with Genetic material from many other people to try to find out what makes some people more likely to get an infection. Some of the tests may be done in different countries.

All information about you will be handled in confidence and only the people responsible for your care and for this study will know that you were a part of the study. We will review your medical records and keep needed information about you on a secure file. All information and samples will be labelled only with a number so that they cannot be directly linked to you personally.

With your permission, we would also like to store your samples and use them for future ethically approved medical research. If you agree to samples being used in future research, your consent form will be retained until the sample has been used up.

The data and samples collected during this study may be looked at by regulatory authorities, authorised individuals from [state your institution here].

Your primary care doctor will be informed that you are taking part in this study.

Are there any benefits to taking part in this study?

There is no benefit to you personally. The information gained from this study may not be available in time to affect your care. Any results available while you are in hospital will be given to your treating doctor. The information we learn may help in caring for other patients in the future.

What are the risks of being in the study?

If you take part in the study and only clinical data is collected from the routine medical records there is minimum risk, all information will be used anonymously (non-study staff will not know that this information relates to you).

If you agree to collect samples, being a part of this study means that more samples will be taken than are needed for normal care. Whenever possible these samples will be taken at the same time as regular samples to reduce the extra procedures. There is a risk of pain or discomfort when samples are taken.

We are going to test for components of the human being that makes an individual unique, to understand their influence on the disease caused by this infection. The results of these investigations are unlikely to have any implications for your future care. For these reasons we will not attempt to identify your child or inform your child of any results from these testing.

Who is responsible and what if something goes wrong?

The research is organised by the [state your institution here], none of who will benefit financially from the study.

If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this study, you should contact the study PIs;

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

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

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.

What about future research?

With your consent, we would like to keep your contact details after your participation in this study is complete, so we may inform you of opportunities to participate in future, research. This is entirely optional and agreeing to be contacted also does not oblige you to take part in any future research.

Your contact details would be stored electronically on a secure server and only the study investigators and authorized staff will have access to it. We will also retain your consent form as long as you are willing to be approached. You can ask us to have your contact details removed from our database at any time.

What if I would like further information about the study?

If you would like more information about the study you can contact the study PIs;

If you have any concern about the conduct of this study, your welfare or your rights as a research participant, you may contact:

[state your institution here]

Local lead investigator:

Clinical characterization and preparedness for COVID-19 disease

INFORMED CONSENT FORM FOR ADULT PATIENT

	Please initial box
I have read (or it has been read to me) the information sheet for this study dated 1st February 2020, version 3.1. I understand the information and have had the opportunity to ask questions for clarification.	
I understand that my participation is voluntary and that I am free to withdraw from the study at any time, without giving any reason and without my medical care or rights being affected.	
I understand that data will be collected from my medical records, including medications and laboratory results by study staff during the study. I agree that these individuals may have access to my research records and their study results.	
I understand that data collected during the study may be looked at by regulatory authorities, authorised individuals from [state your institution here], where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	
I understand that if samples are taken laboratory results from samples collected during the study will be reported to study staff. This information may be looked at by regulatory authorities, authorised individuals from [state your institution here]. I agree that these individuals may have access to my research records and study results.	
I understand that my information can be collected, analysed, reported and shared with others within and outside Africa as part of this study. I understand that my name will not be used and I will not be identified.	
I agree that my fully anonymized samples may be sent elsewhere in the world to be analysed.	
I agree that Genetic material from my blood sample will be analysed to determine whether any genetic factors have made me susceptible to severe infection.	
OR IF YOU DO NOT AGREE, TICK HERE <input type="checkbox"/>	
I agree that my samples, including my Genetic material or those already taken as part of my routine care, and any samples left-over after tests requested by	

<p>the clinicians taking care of me, may be used in additional research in the future, as long as appropriate ethical approval is in place.</p> <p>OR IF YOU DO NOT AGREE, TICK HERE <input type="checkbox"/></p>	
<p>I agree to be contacted directly by the investigators with an invitation to participate in future research studies.</p> <p>OR IF YOU DO NOT AGREE, TICK HERE <input type="checkbox"/></p>	

Patient name: _____

Signature: _____ Date: _____

Person taking consent:

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

Signature: _____ Date: _____

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: _____

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