

Local lead investigators:

Clinical characterization and preparedness for COVID-19 disease

INFORMATION SHEET FOR CONSULTEE

We are undertaking a research study involving people with potential severe acute respiratory infections (SARI) due to emerging pathogen. We are asking you about the participation of an individual who is not able to consent for themselves, because he/she lacks the legal capacity to do so. To help decide if he/she should join the study, we would like to ask your opinion whether or not he/she could be involved but before you decide it is important for you to understand why the research is being done and what it would involve for the participant. 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 the participant's 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. This research study will gain important information about their respiratory infection so we can try to find better ways to manage and treat this infection in the future.

What will happen if the patient takes part in this study?

We will first collect information from the participant routine clinical records such as participant's signs and symptoms, medications that he/she is taking, and the results of any blood test and laboratory results that doctors have ordered when hospitalised. This will happen every day while the participant is in hospital.

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

A blood sample might be taken now together with a swab or suction sample from the participant's nose and throat, a swab from any infected sites/sores, a sputum sample (if they are coughing up mucus), urine sample and a stool sample (or rectal swab if they 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 the participant is unwell up to a maximum of 100 days. We will also invite the participant 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 the patient's weight).

If any other samples are taken from the participant for regular care, and if there is leftover sample after the tests requested by the participant's doctors are done, we will store the leftover to be tested.

What will happen to the information and samples?

All information about the participant will be kept confidential by those working on this study, the patient name or other information 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 severe acute respiratory infection.

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 *[list local agencies here]*, I agree that these individuals may have access to my research records and study results.

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 the participant work in the body. We will also use the blood sample to analyse the participant's Genetic material. We will examine the participant's 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 the participant will be handled in confidence and only the people responsible for the participant's care and for this study will know that the participant were a part of the study. We will review the participant's medical records and keep needed information about the participant on a secure file. All information and samples will be labelled only with a number so that they cannot be directly linked to the participant.

With your permission, we would also like to store the participant's 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 the sponsoring organisation or public health agencies.

The participant's primary care doctor will be informed of they are taking part in this study.

Are there any benefits to taking part in this study?

There is no benefit to you or the participant personally. The information gained from this study may not be available in time to affect the participant's care. Any results available while the participant is 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 the participant takes 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 belonged to the participant).

If agreed to collect samples, being 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 risks. There is a risk of pain or discomfort when samples are taken.

We are doing Genetic material (genetic) tests, to understand their influence on the disease caused by this infection. The results of these investigations are unlikely to have any implications for their future care. For these reasons we would not attempt to identify you or inform you of any results from Genetic material testing.

Who is responsible and what if something goes wrong?

The research is organised by *[list local agencies here]*, none of who will benefit financially from the study.

The *[list local agencies here]*, has arrangements in place to provide for harm arising from participation in the study for which it acts as the Research Sponsor.

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 or the participant 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.

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 their 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 have any problems or 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:

Contact of Local PI here

Local lead investigators:

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CONSULTEE DECLARATION FORM

	Agree	Disagree
I have been consulted about the patient's participation in this research project. 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 the participant's participation is voluntary and that the participant is free to withdraw from the study at any time, without giving any reason and without the participant's medical care or rights being affected.		
I understand that data will be collected from the participant's medical records including medications and laboratory results by study staff during the study. I agree that these individuals may have access to the participant's research records and their study results.		
I understand that data collected during the study may be looked at by regulatory authorities, authorised individuals from <i>[list local agencies here]</i> , 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 <i>[list local agencies here]</i> . I agree that these individuals may have access to my research records and study results.		
I understand that the participant's GP should be informed that the participant is taking part in this study.		
I understand that the participant's fully anonymized information can be collected, analysed, reported and shared with others within and outside Africa as part of this study. I understand that the participant's name will not be used and they will not be identified.		
I understand that the participant's fully anonymized samples may be sent elsewhere in the world to be analysed.		
I understand that Genetic material from the participant's blood sample will be analysed to determine whether any genetic factors have made him/her susceptible to severe infection.		
OR IF YOU DO NOT AGREE, TICK HERE <input type="checkbox"/>		

<p>I understand that the participant's samples, including the participant's DNA and any samples left-over after tests requested by the clinicians taking care of him/her, may be used in additional research in the future, if necessary in different parts of the world, 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 understand for the participant 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>		

Name of consultee: _____

Relationship to participant: _____

Signature: _____ Date: _____

Person taking consent:

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

Signature: _____ Date: _____

Contact details of participant: _____

Address: _____ Phone Number: _____

Witnessed Declaration:

If the consultee 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.