

[Study Title, Research Institution/Facility Name]**Participant information**

Coronavirus disease 2019 (COVID-19) is caused by a virus that belongs to a family of viruses called “Coronaviruses”. Infections of humans with this new coronavirus was first seen in Wuhan in China at the end of 2019, but has now spread around the world including here in [country name]. There is a lot on the News about the spread of COVID-19 disease around the world, and this is also why we have experienced restrictions to our travel and activities, to try and reduce the rate at which people are catching the virus from each other.

Why are we doing this study?

Having COVID-19 might affect someone’s lungs, and their breathing. Some people can be very ill with COVID-19 and need to go into hospital to be cared for, and some people are hardly ill at all. We don’t yet know exactly what causes different levels of illnesses in different people. We know that being older, and having other illnesses like diabetes or hypertension (high blood pressure) at the same time may also increase the risk of having more severe COVID-19 effects, but this is not true for everyone. We are doing this study to understand better what happens to people who have COVID-19, and what might cause them to be more, or less, ill when they have been infected with this coronavirus.

Can I refuse to take part in this study?

You do not have to take part in this study, it is your choice.

If you do not want to take part in this study, you will still receive the same health care. It will **not** affect the health care that you receive in this facility.

We will ask you if you are also interested in taking part in other studies about COVID-19. You do not have to take part in any other studies if you do not want to. It is your choice, and it will not affect including you in this study or the health care you receive in this facility.

What will we ask you for?

We will ask you if you would like to be part of this study.

We will ask for your permission to collect [sample type] from you. We will ask you for ... [provide how much blood e.g. ‘about 2 teaspoons’, when the samples will be collected, what kind of clinical information will be collected and from where e.g. from hospital folders, electronic records, questionnaires]

In the future, there may be other new studies about COVID-19 and other health issues. We will ask you if we can use your information or samples in studies in the future. **You do not have to agree to this, it is your choice.** You can still be part of this study even if you don’t want to be part of other studies in the future.

What will happen to my sample and my health information?**Clinical studies:**

We will collect some extra [sample type] when we collect this [sample type] during your normal health care. We would like to study certain naturally-occurring chemicals in your [sample type], as

these will help us to understand how your body is responding to the coronavirus. We will keep these samples for [provide time frame and storage plans for samples and/or when they will be destroyed]

We will use the sample we collect from you to study the virus that causes COVID-19. This virus has a certain shape and structure that affects how it can make people ill. We will study the chemicals that make up the virus to understand where it came from originally, how it causes illness in people, and to trace how it has been passed on in our population. Studying the structure of the virus from each person who joins the study will also help us to understand if the virus is changing over time.

Genetic studies:

We also want to study something called “genes”. These “genes” are present in all of us and are the same in almost all parts of our bodies. “Genes” are sometimes also called DNA, which is the name of the material they are made from. Genes are responsible for why people in families are often more like each other, and different from other families. For example, some families are generally taller or shorter than others. This kind of information is passed from both the father and the mother to their children and on to their grandchildren, from one generation to the next. Some of these genes may prevent some people from getting certain illnesses. Other genes may be one of the reasons why some people get sick or have side effects from some medicines when others do not. We are still learning how genes might contribute to different diseases, and how they work together with our lifestyle and other factors - such as our environment or what we eat – to affect our health. If someone has several different illnesses at the same time, then these illnesses might also affect each other. We want to explore whether genes and other illnesses occurring at the same time may affect South African patients who have COVID-19.

When we study “genes” it can help us to understand where you and your family come from, because people from the same parts of the world tend to have more similar “genes” than people from very different parts of the world. This is why we will ask you about your family origin, but you do not have to answer this question if you do not want to.

Why am I being invited?

You are invited to take part in the study because you have tested positive for COVID-19 and [study inclusion criteria].

What will happen if I decide to take part in this study?

If you decide to take part in the study, we will use your samples to do the analyses we just told you about. We also want to [...

- Collect some more details about your general health and other health conditions you might have
- Collect more information about the symptoms you have from COVID-19
- Collect additional data about medications you use.
- Look at scans and X-rays if your doctor has ordered these for you.
- Have a follow up visit in xxx months
etc....]

What are the benefits from taking part in this study?

There may be no direct benefits to you from taking part in this study. We will not give you any individual results from the study of the samples you give us. This is because it will probably take a

long time for this project to produce health related information that we will know how to interpret accurately. [Or, provide information about exact results that can be expected from this study, how they will be confirmed, and how they will be provided]. We will gain more knowledge about COVID-19 from this study, and by joining this study you may help us to understand how to best treat patients with COVID-10 in the future.

What are the possible harms when I take part in this study?

Because we will not do any study procedures that your doctor would not already have done, there is no extra physical risk associated with taking part in the study [or provide info on possible physical risks].

The information collected from you will be safely stored on a computer that is password-protected, and your name will be removed from this information so that no-one knows that it comes from you. We will be very careful to ensure that your identity and information is kept confidential and this personal information will not be shared with anyone. We will share the results of this study through scientific publications and also on our website ([URL](#)), but we will make sure that no one knows who participated in this study.

Genetic studies: All your genes together make a special pattern in all of your body that only you have, and this is why no two people are exactly alike. Because each person has their own special pattern of genes, researchers are very careful to protect the genetic samples that are collected and the information from these samples, and these samples and information will only be used in the way we have described here.

Who has approved the study?

The [Review Board Details] has approved this study, and you can contact [name] at [contact details] if you have any questions or concerns, or want to know more about this study.

What if I change my mind?

If you have changed your mind about being part of this study, you can speak to any [doctor/researcher/nurse] or contact [name] at [contact details]. If you do not wish to be part of the study any more, we will destroy your samples and delete any information we have about you. This will not affect the medical care you are receiving in any way.

To reduce spreading the virus, people can wash their hands frequently, cough into a tissue and throw it away in a bin, or cough into their bent elbow, and avoid getting too close to each-other.

People who have COVID-19 have been asked to isolate themselves from other people, because the virus can be easily passed on from someone who has COVID-19, even if they are feeling well and do not have any symptoms.

Wearing a cloth mask in public can also help to reduce the spread of the virus between people who are sharing the same public space.

This pandemic can also impact on your mental health. If you are experiencing anxiety and depression or struggling to cope, please contact counselling services at: [helpline information]

WHAT IS COVID-19?

The name **corona** refers to a crown because these viruses have crown-like spikes on their surface when viewed under an electron microscope.

Human coronaviruses are common throughout the world. There are many different coronaviruses identified in animals but only a small number of these can cause disease in humans.

Some coronaviruses such as 229E, NL63, OC43 and HKU1 are common causes of illness, including respiratory illness, in humans throughout the world. Sometimes coronaviruses infecting animals can evolve to cause disease in humans and become a new (novel) coronavirus for humans.

Examples of these are the Middle East Respiratory Syndrome Coronavirus (MERS-CoV), first reported from Saudi Arabia in 2012, and the Severe Acute Respiratory Syndrome Coronavirus (SARS-CoV), first recognised in China in 2002. On January 9, 2020 the World Health Organization reported that a new coronavirus was identified in China associated with an outbreak of pneumonia in Wuhan City, Hubei Province. This virus is the COVID-19. The majority of the cases/patients initially identified were dealers and vendors at a seafood, poultry and live wildlife market (Huanan Seafood Wholesale Market) in Jianghan District of Hubei Province. This suggests that the novel coronavirus has a possible zoonotic origin. The specific source of the virus is not yet known.

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HOW IS COVID-19 TRANSMITTED?

WHILE THE FIRST CASES PROBABLY INVOLVED EXPOSURE TO AN ANIMAL SOURCE, THE VIRUS NOW SEEMS TO BE SPREADING FROM PERSON-TO-PERSON.

COVID-19 SPREADS VIA RESPIRATORY DROPLETS PRODUCED WHEN AN INFECTED PERSON **COUGHS OR SNEEZES**. SIMILAR TO HOW INFLUENZA AND OTHER RESPIRATORY PATHOGENS SPREAD.

THE MAJORITY OF COVID-19 CASES HAVE OCCURRED IN PEOPLE WITH **CLOSE PHYSICAL CONTACT TO CASES AND HEALTHCARE WORKERS** CARING FOR PATIENTS WITH COVID-19.

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HOW CAN COVID-19 INFECTIONS IN HUMANS BE PREVENTED?

CURRENTLY THERE IS NO VACCINE FOR COVID-19.
OFFICIALS IN CHINA HAVE INTENSIFIED EFFORTS TO CONTAIN THE SPREAD OF THE VIRUS.

THERE ARE NO SPECIFIC MEASURES CURRENTLY RECOMMENDED TO PREVENT COVID-19 BUT THE FOLLOWING CAN PROVIDE PROTECTION AGAINST INFECTIONS WITH CORONAVIRUSES AND MANY OTHER VIRUSES THAT ARE MORE COMMON IN SOUTH AFRICA:

- Wash your hands often with soap and water for at least 20 seconds. If soap and water are not available, use an alcohol-based hand sanitiser.
- Avoid touching your eyes, nose, and mouth with unclean hands.
- Stay home when you are sick and try and keep distance from others at home.
- Avoid contact with farm or wild animals (alive or dead), animal markets, and products that come from animals (such as uncooked meat).
- Clean and disinfect frequently touched objects and surfaces.
- Avoid close contact with people who are sick.
- Cover your cough or sneeze with a flexed elbow or a tissue and throw the tissue in a bin.

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<https://www.nicd.ac.za/diseases-a-z-index/covid-19/infographics/>