

SCREENING AND ENROLMENT INFORMATION SHEET AND INFORMED CONSENT

Each **participant** must receive, read and understand this document **before** any study-related procedure is performed

Study Number:	EZ-FV-028
Study Title:	A cross-sectional, observational study to characterise Long-COVID in an urban sample of South African adults
Short Title:	ChaLOC
Protocol Version and Approval Date:	Version 1.1, 13 April 2022
Sponsor:	Ezintsha, Faculty of Health Sciences University of the Witwatersrand Building C, Sunnyside Office Park 32 Princess of Wales Terrance Parktown, Johannesburg 2193
Funder:	South African Medical Research Council
Principal Investigators (PI):	Prof Francois Venter (PI) Dr Simiso Sokhela (Co-PI) Dr Samanta Lalla-Edward (Co-PI)
Institution:	Ezintsha, Faculty of Health Sciences University of the Witwatersrand Building C, Sunnyside Office Park 32 Princess of Wales Terrance Parktown, Johannesburg 2193
Daytime and After-Hours Telephone Number(s):	082 618 7851 or 064 052 3193

To the potential participant: *This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand. You may take home **an unsigned copy of this consent** form to think about or discuss with family or friends **before making your decision.***

ICF administration starting time: _____

ICF administration finish time: _____

INTRODUCTION

Good day, my name is _____ (INSERT NAME OF STUDY STAFF), I am a _____ (INSERT DESIGNATION) at Ezintsha, a subdivision of Wits Health Consortium.

I would like to invite you to consider taking part in a research study called “A cross-sectional, observational study to characterise Long-COVID in an urban sample of South African adults” or “ChaLOC” for short

- Before you decide if you want to be part of this study, we would like to give you information to help you make an informed decision..
- Please take the time to think through the following information and discuss it with others if you wish. Knowing what is involved will help you decide if you want to take part.
- If you have any questions, do not hesitate to ask me.
- You should not agree to take part unless you are happy about all the procedures involved.
- Please be open with me regarding your health history since you may otherwise harm yourself by taking part in this study.
- If you decide to take part in this study, you will be asked to sign this document to confirm that you understand the study. You will be given a copy to keep.
- If you have a personal doctor, you can inform him/her of you possibly taking part in this study. If you wish, I can also let your personal doctor know.
- As COVID-19 infection is a notifiable disease, should you come to have the disease, we must by law report all cases of COVID-19 to the National Institutes of Communicable Disease (NICD) within 24 hours. Should you agree to take part in the study we will do so without revealing your identity.

1. WHAT IS THE PURPOSE OF THE STUDY?

- COVID-19 is a disease, caused by a recently discovered virus known as SARS-CoV-2. Common symptoms of COVID-19 include fever, tiredness, sore throat, headache, and dry cough and sometimes, muscle ache and pains, diarrhoea, red/sore eyes(conjunctivitis), nausea and loss of taste or smell.
- You can protect yourself and others from getting infected with this virus by regular hand-washing for at least 20 seconds with soapy water, using alcohol-based hand sanitisers, avoiding crowds, keeping a safe distance of about 1,5m from people in general and wearing a face mask over your nose and mouth when in public.
- Most people infected with SARS-CoV-2, will have no or mild symptoms and will recover without needing hospital treatment. However, some people experience post-COVID-19 syndrome which is also referred to as “Long COVID”.
- Long COVID is when you continue to experience symptoms, or experience new symptoms as a direct result of having been infected with COVID, that last for weeks or even months after your COVID infection is gone.
- We currently do not know much about Long COVID and there are no treatments for it. This study aims to describe the features, nature and duration of this syndrome. This information may help us better understand if and why some people experience Long COVID and inform better health outcomes for people experiencing Long COVID.

2. WHY HAVE I BEEN INVITED TO PARTICIPATE IN THIS STUDY?

- You have been invited to take part in this study because you previously had a positive COVID-19 test and you might have shown symptoms, experienced no symptoms, or you may have even been hospitalized from COVID-19. Or you have been invited because you received a vaccine in a clinical trial in 2020.

3. WHAT IF I DON'T WANT TO TAKE PART OR IF I WANT TO WITHDRAW LATER?

- Participation in this study is voluntary. It is completely up to you whether to take part.

- If you decide not to take part, it will not affect any tests or treatment you receive now or in the future for COVID-19, or any other illness. Whatever your decision, it will not affect your relationship with the study staff.
- If you wish to withdraw from the study once it has started, you can do so at any time without having to give a reason and without affecting your medical care.
- If you do decide to take part, you will be given this Participant Information Sheet and Consent Form to sign and you will be given a copy to keep.

4.WHAT IS THE LENGTH OF THE STUDY AND NUMBER OF PARTICIPANTS?

- A total of 400 participants will be invited to participate in this study.
- You will be required to visit the site for a single visit (of approximately 6 hours), or two or more visits depending on whether you agree enrol into any of the sub-studies.
- If you agree to participate in the sleep sub-study, you will have an overnight admission at the Wits Faculty of Health Sciences sleep laboratory.
- The total amount of time required for your participation in this study will be a maximum of 3 months.
- Participants will be aged 18 years and older.

5.WHAT DOES PARTICIPATION IN THIS RESEARCH INVOLVE?

- This study will not take a lot of your time.
- Before starting participation in the study, you will be seen by both a nurse and a doctor who will ask you questions and examine you to see if you qualify for this study.

Screening = Day 1:

Your study doctor or nurse will:

- Discuss the ChaLOC study with you, and if you choose to take part you will sign and date the Consent Form
- Collect information about your COVID-19 infection history and your vaccination status.
- The information collected about you at this visit will be used to decide if you will be included in this study. You will also be asked to provide your contact details as well as those of a close family member/friend, to allow the study staff to contact you (also using WhatsApp and/or sms) for visit reminders and any other study related information.

If you qualify to be enrolled in the study, you will be required to fast 8 hours before coming to site for your enrolment visit.

Baseline = Day 1- 7:

After the study nurse or doctor has confirmed that you are eligible to be enrolled in the study, the following procedures will be conducted:

- Draw a maximum of 70mL (14 teaspoons) of blood for targeted laboratory testing including, haematology and chemistry (including liver and kidney functions), glucose, HbA1C, inflammatory markers assessments, and for DNA extraction for genotyping and sequencing.
- If you agree to storing of your blood and urine samples, you will be required to sign a separate consent form and 50mL (10 teaspoons) of your blood and 100mL (20 teaspoons) of your urine will be collected to be stored for future research

- Collect your demographic information, your social background and use of tobacco, alcohol, or drugs
- Review any medical notes and collect your medical and medication history, including your COVID-19 history
- Record your height, weight, vital signs (blood pressure, heart rate, and temperature)
- Administer several questionnaires which will be evaluating general health, psychological issues, psychosocial factors, work performance, sleep and pain.
- An ECG will be performed, and you will be required to complete a six-minute walk test to assess your cardiac activity.
- You will be contacted telephonically within 28 days of completion of your baseline visit to inform you of the results of your assessments. If there are abnormalities detected, you will be referred out to relevant institutions for further investigations and management.
- You will also be offered an optional HIV test. The HIV test is not compulsory. If you agree to the test you will have to complete a separate consent form.
- After the initial visit tests and questionnaires are reviewed by the investigators, you may be invited to participate in one or more of the five sub-studies to further assess how Long COVID affects the lungs, heart, sleep, pain and how your body processes sugar. If you agree to participate, you will complete a separate consent form and can choose to participate in more than one of the sub-studies.

6.DO I HAVE TO TAKE PART?

- No, participation is voluntary. It is completely up to you whether to take part.
- If you decide not to take part, it will not affect any tests or treatment you receive now or in the future for COVID-19, or any other illness. Whatever your decision, it will not affect your relationship with the staff caring for you.
- If you wish to withdraw from the study once it has started, you can do so at any time without having to give a reason and without affecting your medical care.
- If you do decide to take part, you will be given this Screening and Enrolment Consent Form to sign and you will be given a copy to keep.

7.HOW IS THIS STUDY BEING PAID FOR?

This study is being funded by South African Medical Research Council and conducted by the Ezintsha research team.

8.WHAT ARE THE POSSIBLE RISKS AND DISADVANTAGES OF TAKING PART?

Risks associated with taking part in this study include:

Risks of drawing blood

As part of this study, you will have your blood drawn as described above. This procedure is slightly uncomfortable but very rarely results in any major problems. Side effects that have been noted with drawing blood include feeling light-headed or faint, fainting, formation of a blood clot, bruising and/or infection at the site of the injection.

9.WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

We cannot guarantee or promise that you will receive any benefits from taking part in this study.

By taking part in this study, you may contribute new information that may benefit patients who have the Long COVID-19 syndrome in the future.

10.WILL TAKING PART IN THIS STUDY COST ME ANYTHING, AND WILL I BE PAID?

Participating in this study will not cost you anything. You will not be paid for participating in this study, but you will be compensated for time and inconvenience. A compensation amount of R650 will be given to you at the enrolment visit. Participation in the sub studies will be compensated for separately, depending on the duration of each sub study. This will be discussed with you when you are invited to participate in these.

11.HOW WILL MY CONFIDENTIALITY BE PROTECTED AND WHAT WILL HAPPEN TO INFORMATION ABOUT ME?

Your confidentiality will be protected as explained to you by the study staff and detailed in the study's Participant Information and Consent Form. We summarise the information below.

Of the people assessing you, only the study doctor and research team involved in your care will know whether you are participating in this study. Any information collected that can identify your connection with this study will be kept confidential and will be shared only with your permission, or as required by law. Your health records and any information gathered during the research project may be subject to inspection (to check the procedures and information gathered) by the relevant authorities, the Sponsor and/or authorised representatives of the Sponsor and the institution relevant to this Participant Information Statement at the study site or as required by law.

Your study records might also be reviewed by the National Health Research Ethics Council (NHREC) and University of the Witwatersrand Human Research Ethics Committee (HREC).

By signing the consent form, you consent to the research team collecting and using information about you for the research study.

The research team will store the data collected from you for this research project for a minimum of 15 years after the publication of research results. The information about you will be stored in a re-identifiable format where any identifiers such as your name, address, date of birth will be replaced with a unique code. Only the research team can match your name to the unique code if it is necessary to do so.

You will be asked to provide your consent for the research team to share or use the information collected from you in future research in the same general area of research. All future research will need to be approved by the University of Witwatersrand HREC before proceeding. Your information will only be shared in a format that will not identify you.

Information collected from you in an electronic format will be stored in secure password protected databases only accessible to the approved research investigators. Information collected from you using paper records will be stored in a locked cabinet at the Ezintsha clinical trial site, and only the approved research investigators will have access to this information.

Your data will be collected, processed and stored according to the South African Protection of Personal Information (POPI) Act of 2013

12.WHAT WILL HAPPEN WITH THE STUDY RESULTS?

By signing the Consent Form, you consent to the study doctor and relevant research staff collecting and using personal information about you for this research project. Any information obtained in connection with this research project that can identify you will remain confidential. Your information will only be used for the purpose of this research project, and it will only be disclosed with your permission, except as required by law.

The results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified. Results of the study will be provided to you.

13.NEW FINDINGS

I will provide you with any additional information that becomes available during the study, which may affect your willingness to continue on the study

14.ETHICAL APPROVAL:

- This study protocol has been submitted to the University of the Witwatersrand, **HREC** and written approval has been granted by that committee.
- The study has been structured in accordance with the **Declaration of Helsinki** (last updated: October 2013), which deals with the recommendations guiding doctors in biomedical research involving human participants. A copy may be obtained from me should you wish to review it.

15.SOURCE OF ADDITIONAL INFORMATION:

- For the duration of the study, you will be under the care of qualified medical doctors and nurses. If you have questions at any time during the study, please do not hesitate to contact the study staff.
- **The 24-hour telephone number** through which you can reach me, or another authorised person is 082 618 7851 or 064 052 3193.
- If you want any information regarding your **rights as a research participant, or complaints regarding this research study**, you may contact Prof. Clement Penny, Chairperson of the University of the Witwatersrand, Human Research Ethics Committee (HREC), which is an independent committee established to help protect the rights of research participants at (011) 717 2301.
- For **research information** you can contact Prof Francois Venter at 082 618 7851 or 064 052 3193

PARTICIPANT QUESTIONS:

Did the participant raise any questions? **YES** ☐ / **NO** ☐

If YES – What were they and what was the answer provided:

INFORMED CONSENT

Declaration by the participant

- I understand I am being asked to provide consent to participate in this research study.
- I have read the Participant Information Sheet, or someone has read it to me in a language that I understand.
- I understand the purposes, study tasks and risks of the research described in the study.
- I provide my consent for the information collected about me to be used for the purpose of this research study only.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- I freely agree to participate in this research study as described and understand that I am free to withdraw at any time during the study. Withdrawal will not affect my relationship with any of the named organisations and/or research team members or any care.
- I understand that I will be given a signed copy of this document to keep.
- I understand that the global results of the research will be made available to me and may be published in various media, including on the Ezintsha website.

PARTICIPANT:

Printed Name(s) and Surname

Signature / Mark or Thumbprint

Date and Time

I, _____, herewith confirm that the above participant has been fully informed about the nature, conduct and risks of the above study.

INFORM CONSENT ADMINISTRATOR:

Printed Name(s) and Surname

Signature / Mark or Thumbprint

Date and Time

WITNESS (If applicable):

Printed Name(s) and Surname

Signature / Mark or Thumbprint

Date and Time

INVESTIGATOR:

Printed Name(s) and Surname

Signature / Mark or Thumbprint

Date and Time