INFORMED CONSENT FORM

This consent form is for everyone age 18 years old and older who attends the Participating Centre for medical services and attention and who is invited to participate in a promising clinical trial to potentially prevent the progression and transmission of COVID-19, an infectious disease that has currently affected approximately 1.3 million people and claimed the lives of close to 70,000 individuals around the world.

The consent form will enable you to participate in the study entitled:

Combined Use of Oral Lysosomotropic Agents to Hinder the Onset, Transmission and Progression of COVID-19: An Open Randomized Clinical Trial

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This Consent Form has two parts:

1. An Information Sheet describing the study.

2. A Consent Form to be signed by those who wish to voluntarily participate in the study.

Please carefully read the information sheet. If, after reading the information provided, you would like to participate, please sign the Consent Form. If you have any questions prior to making your decision or wish to have further information, please let us know. We will be pleased to assist you.

INFORMATION SHEET

What is COVID-19?

COVID-19 is an infectious disease caused by a respiratory Coronavirus called SARS-CoV-2. In early December 2019, this virus first infected people in Wuhan, the capital city of Hubei province in central China. This virus causes severe damage to the lungs of infected people causing pneumonia and other life threatening conditions. COVID-19 is present in most countries around the world and, therefore, it has been considered a pandemic disease since March 11, 2020, by the World Health Organization (WHO). Today, approximately 1.3 million people have been diagnosed with COVID-19 around the world, of which 70,000 individuals have died.

Is there any vaccine or cure for COVID-19?

There is no current cure or vaccine to treat COVID-19. Several research groups and organisations, including ours, are rapidly advancing very promising experimental treatments and vaccines. Participation in clinical studies by patients with confirmed cases of COVID-19 will help us to find better treatments to control and to get rid of this severe disease.

What is the study, and how can I benefit from my participation in it?

This study will help us to determine the potential use of already clinically approved drugs such as Chlorpromazine, Hydroxychloroquine Sulphate, Azithromycin and Doxycycline for the treatment and prevention of COVID-19 . Your voluntary participation in this study could benefit you through access to a potentially beneficial treatment that could reduce the impact of COVID-19 on your health and that of your family and loved ones. To maintain the study's objectivity, participants will be randomly selected as part of the experimental protocol or as controls. However, all participants, control and experimental individuals, will be provided with the best standard care available at your Participating Institution for the current available management of COVID-19 regardless of which group they are assigned to.

What are potential side effects of the proposed experimental treatment?

Chlorpromazine, Hydroxychloroquine Sulphate, Azithromycin and Doxycycline have all been safely and successfully used for various health conditions for several years. Like any other pharmaceutical drug, there is the possibility of undesirable side effects such as nausea,

anxiety, insomnia, drowsiness, sedation, dry mouth and headache. More serious adverse reactions such as allergies to the medication, chest discomfort or pain, blurred vision, dark urine and uneven heartbeat have also been reported. Close medical supervision and intervention will be provided to all participants. If any adverse reaction results from any of the experimental treatments, participants will be removed from the study and be provided with the standard clinical management of COVID-19 in your institution.

Voluntary Participation

Participation in the study is strictly voluntary without any financial benefit or costs to the participants. Your decision not to participate in the study will not change, in any way, the standard and best clinical management as a patient suffering from COVID-19.

Duration of the Study

Participants will be enrolled in the study within 48 hours of being clinically confirmed as suffering from COVID-19 using a selective test and clinical assessment within your institution. Once enrolled, patients will participate in the study for a maximum of 14 days with an individual follow-up as required.

Confidentiality

All information gathered during the study will remain strictly confidential without revealing the name and health status of any participant. Participants will be given a sequential number after the number of the Participating Institution (for example: 1-0001, 1-0002, 1-0003); the first number, in bold, is the number of the Participating Institution.

Information Sharing and Publication of Results

In order to advance and share the benefits resulting from this study, all participants grant the right to anonymously share all clinical outcomes resulting from this study with the principal investigators and coordinators of this study. Results from this study will also be anonymously available through scientific publications and reports.

CONSENT FORM

I have read the content provided in the Information Sheet, or its content has been read to me. I have had the opportunity to ask questions about the content of the Information Sheet, and any questions that I have asked have been answered to my satisfaction. I voluntarily consent to take part as a participant in this research study.

Name of Participant (Printed): _____

Signature of Participant: _____

Date: _____

Year / Month / Day

Illiterate

I have witnessed the accurate reading of the Consent Form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely and without remuneration.

Name of Witness (Printed): _____ AND Thumb Print of Participant

Signature of Witness: _____

Date: _____

Year / Month / Day

Statement by the Researcher / Person Taking the Consent

I have accurately read aloud the Information Sheet to the potential participant and, to the best of my ability, made sure that the participant understands that the following will be done:

1. Random assignment to an experimental or control group without affecting current standard available clinical management of COVID-19.
2. Experimental treatment with drug combinations that, depending upon the assigned group, may include Chlorpromazine, Hydroxychloroquine Sulphate, Azithromycin and Doxycycline. Some undesirable potential side effects of these drugs were also explained.
3. Perform clinical analysis including additional regular testing for COVID-19.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent and that the consent has been given freely and voluntarily without any remuneration.

A copy of this Informed Consent Form has been provided to the participant.

Name of Researcher / Person Taking the Consent (Printed): _____

Signature of Researcher / Person Taking the Consent: _____

Date: _____

Year / Month / Day