

# **WORLD HEART FEDERATION (WHF) COVID-19 and CVD Survey**

## **Participant Information Sheet and Informed Consent Form**

### **Participant Information**

You have been admitted to hospital with a diagnosis of Coronavirus disease (COVID-19) and will be treated according to the best standard care treatment offered by your hospital and Doctor.

COVID-19 is caused by a coronavirus named SARS-CoV-2. Signs and symptoms of COVID-19 include flu-like symptoms such as fever, cough, tiredness, headache, sore throat, shortness of breath and sore muscles. In rare cases nausea, vomiting and diarrhoea have occurred. In severe cases, pneumonia, acute respiratory distress syndrome multi-organ failure and death have been reported.

### **What is the Purpose of this Study?**

We would like to invite you to take part in a large study that is being conducted all over the world, organised by the *World Heart Federation*.

The purpose of this survey is to describe cardiovascular outcomes among patients hospitalized with COVID-19 and to identify cardiovascular risk factors associated with poor in-hospital outcome in patients with COVID-19, in different countries and in different settings throughout the world. The results of the research will lead to important suggestions for improvement in the treatment of COVID-19 and cardiovascular disease (CVD) around the world.

### **Why have I been chosen?**

All patients with a confirmed diagnosis of COVID-19 infection who have been referred to (Name of Dr ..... ) are being invited to participate in this study. We hope to recruit a total of 5,200 patients from many countries into the study.

### **Do I have to take part?**

No, you do not have to participate in this study, and you do not have to give reasons for declining to do so. Your usual care will not be affected if you decide not to take part. If you do decide to take part in the study, you may change your mind and withdraw from the study at any time, without giving a reason, and this will not affect your future treatment and care.

If you do decide to take part, you will be asked to sign the consent form below. You will be given a copy of the consent form to keep.

### **What will happen to me if I take part?**

We will collect data concerning your past medical history and the treatment you received; diagnostic tests that are performed during your stay at this hospital and any current treatment you are receiving.

We would also like to interview you at discharge and again at 30-days after enrolment to ask you about any further investigations and adverse events (consequences of COVID-19) you may have had. The 30-day follow-up can be conducted over the telephone or you can attend the hospital clinic for the interview.

### **What do I have to do?**

It will not be necessary for you to undergo any medical tests or treatments; other than the normal care you would receive for your condition. No treatments will be withheld as a result of you taking part in this research project. Your care will continue as normal under the care of your Doctor.

### **What are the possible disadvantages and risks of taking part?**

You will not be exposed to any risks or hazards by taking part in this study, which only collects routine clinical information.

### **What are the possible benefits of taking part?**

There will be no immediate or direct benefit to you if you decide to take part in this study. However, we hope that the information we gather about you and patients like you, will help us to improve the future care of patients with COVID-19 infections and heart disease.

**Costs and compensation**

There are no costs attached to this study and you will not receive compensation for participation.

**What if I have any concerns about this research project?**

The investigator or research nurse/doctor in charge of the study, will be happy to answer any questions you may have about this study or the way it is being carried out.

**Will my taking part in this study be kept confidential?**

Yes, the information collected about you will remain strictly confidential, according to the law of your country. Your data will not have your name on it, instead a confidential study number will be assigned to your data and kept in the local database, which will ensure that all data transferred to the central database will be kept anonymous. It will not be possible for anyone who is not connected with this study to access any personal or medical information we may have about you.

The study has been approved by <enter the Institution and Human Research Ethics committee names> for compliance with medical and ethical standards. In addition, the study will be conducted according to the Declaration of Helsinki (Fortaleza, 2013) and Good Clinical Practice Guidelines, as specified by the International Conference on Harmonisation (ICH) and the United States Food and Drug Administration (FDA). If you want any information regarding your rights as a research participant, or have complaints regarding this research, you may contact <enter the name of your Human Research Ethics committee Chairperson and the telephone number>, the Chairperson of the Human Research Ethics Committee at the <enter the Institution name> and give them the Study Ethics committee reference no: < enter the HREC Ref no>.

**What will happen to the results of the research study?**

It is expected that the results of the study will be published in relevant medical journals and presented to cardiologists and other health professionals who have an interest in this area. It will not be possible to identify you from the published results of this study because data will be collected in a completely anonymous way. You may request a copy of any published results from the investigator. The study data once analysed and published will be stored for a maximum of 15 years.

Thank you for taking the time to read about this study which, we hope, will improve the care of patients with COVID-19 and heart disease in the future. Please ask the researcher if you have any questions or would like more information about the study. Contact details for the investigator and research nurse/doctor are given below:

**Investigator/researcher:**

Name and contact details .....  
.....

**Research nurse:**

Name and contact details .....  
.....

If you need further information or have any questions about this study, please do not hesitate to contact the researcher or data collecting person in charge of this study.

Thank you for your help and assistance regarding this international study which we hope will enable improvement of the care of patients with COVID-19 and heart problems soon.

**If you do not wish to take part this will not affect your usual care in any way**

## Patient Consent

- I confirm that I have read the information form and that I understand the information. I have had the opportunity to ask additional questions and have had adequate replies to my questions. I have had enough time to consider participation.
- I am aware that my participation is completely voluntary.
- I authorize the following persons, namely: members of the medical research team; members of the ministry of public health; members of the medical ethics committee; local auditors or other competent authorities, to have access to my medical files and study data.
- I consent to the storage of my personal information for up to 15 years after completion of the study.
- I understand that the data obtained will only be used for scientific research purposes.
- I agree to the use of my data as explained in the *Participant Information* sheet and consent to participate in the WHF COVID-19 and CVD survey.

Date:		
Patient Name:		Signature
Legally acceptable representative (LAR) Name:		Signature
Impartial witness Name		Signature
Investigator Name:		Signature
Name of the person (medical doctor or research nurse), who informed the patient:		Signature
For further information please contact the researcher:		Contact details