HOSPITAL DAS CLÍNICAS OF THE SCHOOL OF MEDICINE AT THE UNIVERSITY OF SÃO PAULO – HCFMUSP

TERMS OF INFORMED CONSENT FORM

RESEARCH DATA

Research Title - **"FAPO-X: Assisted digital telemonitoring with wearables in patients undergoing cardiovascular surgery postoperatively - a randomized study''.**

Principal Investigator - Prof. Dr. Fabio Biscegli Jatene

Department/Institute - Division of Cardiovascular Surgery at InCor

Invitation to participate – You are being invited to participate in a study that aims to evaluate whether a smartwatch connected to a mobile phone can help provide reliable data on your blood pressure, heart rate, rhythm, oxygen saturation, and sleep.

1. Justification and study objectives

This study aims to evaluate whether a smartwatch can identify irregularities in your heart rate and other cardiac parameters, as well as enable remote monitoring of these parameters. To achieve this, we will analyze clinical data from patients who, like you, will undergo cardiac surgery. After discharge from the hospital, some patients may experience cardiac arrhythmias, meaning that the heart may beat faster or slower than normal. The smartwatch will allow your doctor to remotely monitor your heart rhythm, even while you are at home.

This study has the potential to contribute to a future where all patients can be monitored by the clinical team while in the comfort of their homes, enabling the physician to identify any abnormalities and provide prompt action and guidance to the patient, thereby reducing risks.

2. Composition of study groups

The study will consist of two groups: one group that will follow the standard hospital flow with discharge and a scheduled follow-up appointment after surgery, and another group that will receive a smartwatch on loan for measuring certain vital signs such as blood pressure, heart rate, rhythm,

oxygen saturation, and sleep. A random drawing will determine whether the patient will receive the smartwatch or not.

You may be selected to be part of the teleassisted group, providing remote data to our electronic medical record system automatically through a smartwatch (for approximately 30±3 days), or you may be part of the control group, which will serve as a comparison standard with individuals monitored by the smartwatch. This study aims to contribute to the future utilization of these devices as a reliable tool for remote monitoring of patients with atrial fibrillation.

3. Procedures to be performed and methods to be employed

If you agree to participate in the aforementioned research, there will be no alteration to your treatment. Only patients who are randomly selected to participate in the **teleassisted** group will receive a smartwatch upon their discharge from the hospital after the Cardiovascular Surgery.

To evaluate the accuracy of the data provided by the device, we will compare the results with those obtained from gold standard reference equipment, which are:

Electrocardiogram: This is a test that evaluates the electrical activity of the heart using electrodes attached to the skin. It helps detect the heart rhythm and the number of beats per minute. You will lie down on a hospital bed in a resting position for 10 minutes before the procedure to ensure that the results are not influenced by external factors. Then, the electrodes will be placed on your chest, wrists, and ankles.

Blood Pressure: Measuring blood pressure is a safe way to assess the levels of blood pressure in your body. It involves measuring the values of systolic (high) and diastolic (low) pressure to determine whether the tension levels correspond to normal parameters or if there is a diagnosis of hypertension.

Oximetry: Pulse oximetry is a method of measuring how much oxygen your blood is carrying. Using a small device called a pulse oximeter, your blood oxygen level can be measured without the need for needle puncture. Ideally, more than 89% of your red blood cells should be carrying oxygen.

Following these assessments, patients in the teleassistance group will receive instructions on how to wear and use the smartwatch connected to their mobile phones, which will be loaned to you for the 30-day remote monitoring period.

At no time will you be subjected to invasive examinations or procedures as part of this study.

4. Explanation of possible discomforts and risks arising from participation in the research

This smartwatch does not cause any discomfort. The exams that you will undergo are routine hospital exams. There are no additional risks in this study. Your participation in the FAPO-X Protocol does not involve any changes to your treatment. As with any clinical study, there is a possibility of indirect risks in psychological, moral, intellectual, social, or cultural aspects, such as feeling uncomfortable when answering a question. If this happens, you may refuse to answer without any negative consequences for your participation in the research.

To prevent the breach of confidentiality of your personal data, you will be identified in the study records by a numerical code. The study data will be treated in a coded manner. The records of your participation in this study will be kept confidential. Your data will be accessed restrictedly by individuals involved in the study who will transfer your clinical information to forms and verify the appropriate conduct of the study. Your confidentiality is protected by the Data Protection Law of August 14, 2014.

Expected benefits for the participant – As a benefit, you will have the opportunity to be monitored daily by specialists and a multidisciplinary team after the surgical procedure. Your participation in this study aims to demonstrate the reliability of this device in detecting your vital signs, and it will be valuable for making improvements in the accuracy of the smartwatch.

5. Clarification on the form of follow-up and assistance to which research participants will be entitled

- ✓ All information obtained in this study will be treated with complete confidentiality, secrecy, and privacy.
- ✓ If you were to suffer any physical harm as a direct result of the procedures performed, you will receive all necessary medical care provided by the Heart Institute. If the Institute is unable to provide such medical care, you will be reimbursed by the party responsible for the harm, and this reimbursement will be made according to common and reasonable medical expenses incurred in the treatment of said physical harm.

- ✓ If you suffer any physical harm as a result of the procedures required by the study, you will be reimbursed for usual and reasonable medical expenses actually incurred in the treatment of such harm and not covered by hospital insurance or other third-party coverage, provided that the harm is not due to your failure to follow the instructions contained in the informed consent form or communicated by the study investigators. These medical care expenses should be obtained by you in the same manner as you would normally obtain other medical treatments. No other provision has been made for financial reimbursement or other forms of compensation (such as loss of wages, loss of work days, or discomfort) in relation to such harm; however, by signing this form, you are not waiving any of your legal rights.

At any stage of the study, you will have access to the research professionals for clarification of any doubts. The principal investigator is **Dr. Fabio Biscegli Jatene**, who can be reached at the following address: **Avenida Dr. Enéas de Carvalho Aguiar 44**, **5th floor - Block II**. **Phone: +55 11 91080-0383 and +55 11 2661-5197, email: suporte.inovaincor@gmail.com**. If you have any concerns or questions regarding the ethics of the research, please contact the Research Ethics Committee (CEP) at the following address: Rua Ovídio Pires de Campos, 225, 5th floor - phone: +55 11 2661-7585, +55 11 2661-1548, +55 11 2661-1549, from 7 am to 4 pm, Monday to Friday, or by email: cappesq.adm@hc.fm.usp.br.

I have been sufficiently informed about the study "FAPO-X: Digital Telemonitoring Assisted with Wearables in Patients in the Postoperative Period of Cardiovascular Surgery - a Randomized Study."

I have discussed the above information with the Principal Investigator (Dr. Fabio Biscegli Jatene) or person(s) delegated by him (.....) regarding my decision to participate in this study. The objectives, procedures, potential discomforts and risks, and guarantees have been made clear to me. I voluntarily agree to participate in this study, sign this informed consent form, and receive a copy initialed by the researcher.

---------- Date____/____/_____

Participant/legal representative's signature

Name of participant/legal representative.

---------- Date ____/____/_____

Signature of study investigator