Hospital das Clínicas of the Faculty of Medicine of the University of Sao Paulo – HCFMUSP

(INFORMED CONSENT FORM)

Research Data

Research Title – "**FAPO-2: Cardiac Patient Monitoring Tool for Clinical Observation and Arrhythmia Detection"**

Principal Investigator – Prof. Dr. Fabio Biscegli Jatene

Department/Institute – Cardiovascular Surgery Division of InCor

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

1. Rationale and Objectives of the Study - This study aims to collect health parameter data through a device capable of identifying irregularities in your heart rhythm, similar to a Holter monitor, along with other cardiological parameters, allowing remote monitoring of these parameters. To achieve this, we will analyze clinical data from patients undergoing outpatient cardiology follow-up or those who have undergone minimally invasive cardiac procedures.

Some cardiac patients may experience arrhythmias, meaning the heart may beat faster or slower than normal. The devices in this study will allow your doctor to remotely monitor your heart rhythm, even while you are at home. This study may help ensure that, in the future, all patients can be monitored by the clinical team while at home, enabling doctors to detect abnormalities early and act promptly to reduce risks.

2. Study Groups

The study will consist of four groups: a pilot group, two groups of patients in outpatient clinical follow-up, and a group of patients undergoing minimally invasive cardiovascular interventions.

- **Pilot Group (n=15):** Healthy volunteers without a history of arrhythmias or heart disease to validate device usability and functionality.
- **Extensive Outpatient Monitoring Group (n=150):** Patients with chronic heart diseases under outpatient follow-up, monitored remotely for 30±3 days. During the first 14 days, the Huinno™ MEMO Patch and the Samsung Galaxy Watch 6 will be used, with Samsung Health and Samsung Health Monitor apps. After this period, monitoring will continue exclusively with the smartwatch until completing the 30±3 days.
- **Condensed Outpatient Monitoring Group (n=305):** Patients with chronic heart diseases under outpatient follow-up, monitored remotely for 15±3 days, using the Huinno™ MEMO Patch and the Samsung Galaxy Watch 6 for the first 14 days, followed by smartwatch-only monitoring until the end of the 15±3 days.
- **Post-Cardiovascular Intervention Monitoring Group (n=50):** Hospitalized patients who have undergone minimally invasive cardiac interventions or surgeries, such as ablation for arrhythmias, transcatheter aortic valve implantation, or angioplasty. These patients will be monitored remotely for 30±3 days using the Huinno™ MEMO Patch and the Samsung Galaxy Watch 6 for the first 14 days, followed by smartwatch-only monitoring until completing the 30±3 days.

Device Usage

All groups will receive a smartwatch (Samsung Galaxy Watch 6), a mobile phone, and a portable device (Huinno™ MEMO Patch) for heart rhythm monitoring. The smartwatch will measure vital signs, including blood pressure, heart rate and rhythm, oxygen saturation, and sleep quality. The portable device, similar to a Holter monitor, will capture and store heart rhythm data, enabling detailed analysis at the end of the monitoring period.

Regardless of the group you are assigned to, you will provide remote data to the electronic medical record automatically during the monitoring period (15±3 or 30±3 days, depending on the group).

3. Procedures and Methods

If you agree to participate, your treatment will not be altered. You will only receive device(s) and have your health data monitored in real-time by a clinical team.

To assess the accuracy of smartwatch data, we will compare the results with standard gold-reference methods, such as:

Electrocardiogram (ECG): Evaluates heart electrical activity using electrodes placed on the skin to detect heart rhythm and beats per minute. You will lie on a hospital bed for 10 minutes before the procedure to minimize external influences. Electrodes will be placed on your chest, wrists, and ankles.

Blood Pressure Measurement: Determines systolic (high) and diastolic (low) blood pressure levels to assess normality or hypertension diagnosis.

Oximetry: Measures oxygen levels in your blood using a pulse oximeter without the need for needle punctures. Ideally, more than 89% of red blood cells should carry oxygen.

Participants in the Clinical Group using the Holter-like device for heart rhythm monitoring will wear it for 14 days. Detailed instructions on correct usage, cleaning, and skin care will be provided.

At no point will you undergo invasive tests or procedures due to this study.

4. Potential Discomforts and Risks

The smartwatch is comfortable, like any regular watch. However, the adhesive used for the heart rhythm monitoring device may, in rare cases, cause temporary skin irritation or redness. Skin evaluations and care instructions will be provided to prevent lesions.

All tests conducted are part of routine hospital procedures, with no additional risks. Participation in the FAPO-2 protocol does not alter your treatment plan. As with any clinical study, there may be indirect risks, such as feeling uncomfortable answering questions. You may refuse to answer any question without affecting your participation.

To protect your data confidentiality, you will be identified by a numeric code. All collected information will be handled securely and shared only with directly involved study personnel. Data collected will be shared with Samsung Electronics Co., Ltd., for future research and securely transferred via the CPCex (Data Security Platform) of Samsung Electronics, ensuring data integrity and confidentiality in compliance with the Data Protection Law of August 14, 2018.

Expected Benefits for Participants – Participants will receive daily monitoring by specialists and a multidisciplinary team after surgery. Your participation will help validate the smartwatch's accuracy and contribute to future improvements.

5. Follow-Up and Assistance:

- ✓ Throughout the study, participants will have access to medical professionals for any concerns or clarifications. If you experience any medical issues related to the study, you will receive appropriate care from InCor. Should InCor be unable to provide the necessary medical treatment, reasonable medical expenses will be reimbursed, provided they are directly related to study procedures.

- ✓ Participants are encouraged to comply with study protocols and communicate any issues to the research team. While financial compensation for lost wages or personal inconveniences is not provided, participating in the study does not waive any of your legal rights.

At any stage of the study, you will have access to the research professionals responsible for clarifying any doubts. The principal investigator is Dr. Fabio Biscegli Jatene, who can be reached at 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 Rua Ovídio Pires de Campos, 225 – 6th floor – CEP 05403-905 – Phone: +55 11 2661-7585, +55 11 2661-1548, Monday to Friday from 7 AM to 4 PM, or by email: cappesq.adm@hc.fm.usp.br.

I have been sufficiently informed about the study “FAPO-X: Digital Assisted Telemonitoring with Wearables in Postoperative Cardiovascular Surgery Patients – A Randomized Study.”

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

Date: _____/_____/_____ Participant Signature: _____