PATIENT INFORMATION SHEET AND INFORMED CONSENT FORM

Confidential

STUDY TITLE: LONGITUDINAL ASSESSMENT OF ELECTROCARDIOGRAPHIC ABNORMALITIES IN OUT PATIENTS AT HIGH CARDIOVASCULAR RISK USING PORTABLE ECG DEVICE

Study No. ERIS/OS/ Version No.: Dated:

Patient Information:
Patient No: | | | | | | | | | | | **Patient initials:** | | | |

DETAILS ABOUT THIS PARTICULAR STUDY ARE PROVIDED IN THE FOLLOWING PAGES. PLEASE READ THIS INFORMATION CAREFULLY AND ASK ANY QUESTIONS YOU MAY HAVE

This document is summary of what this study is all about, what you are required to do and how it may affect you. If you have any questions, it is your responsibility to ask it and get it answered to your satisfaction before you sign the declaration.

I. Introduction:

You are invited to participate in this study. It is important that you read this description of the study and understand your role in it.

Please give your consent to participate in this observational (watch), study only if you have completely understood the nature and course of this study and if you are aware of your rights as a participant. Feel free to ask any questions before signing this document.

II. Purpose of the study:

To screen early for ECG abnormalities in high CV risk patients (smoking, obesity, diabetes, hypertension, aging population, sedentary lifestyle, family history of CVD) using handheld ECG device.

III. Expected duration of the study and number of subjects:

You will have to visit site as per study investigator's recommendation. A approximately of 30,000 subjects aged 40 years or above (both inclusive) will be enrolled in this study. The study duration will be about 5 year.

IV. Study procedures to be followed:

Once your study doctor finds you to be a potential participant in the study, he will explain the study details. If you willingly and voluntarily agree to participate in the study, your study doctor will ask you to read, understand, and sign this consent form.

You will have to undergo thorough vital signs assessment, and details about your demographics and anthropometric (Age, weight, Height, BMI, Waist circumference), lifestyle, family, medical and medication history would be recorded at the baseline.

Your Dr. will ask you to take ECG with hand-held device, please follow the instruction to complete the screening of 30 sec each. Details given in table below.

Reading 1: Normal 6L ECG	30s each (Total 90 seconds)
Reading 2: Single lead ECG at V1	
Reading 3: Single lead ECG at V6	

V. Risk-Benefit Assessment

Since the study is designed as observational study, estimated risk for participants is not greater than minimal risk. Data generated will be useful to the physicians in diagnosis and treatment of future subjects. The study possesses very low risk to the subjects. The benefit for the patients in this study will be early detection of ECG abnormalities especially patients with high CV risk.

VI. Confidentiality:

Your participation in this research study will be kept confidential and your identity will not be disclosed in any publication of the results of this study. However, this research record and your personal medical record (if required) may be reviewed by government agencies, by the company sponsoring this research, or the ethics committee that oversees the results of the study. All the analyzed data from the study will be provided (for reporting or publication purpose to regulatory/other agencies) without your personal identifying information such as your name and address.

VII. Compensation for participation:

Since the study is designed as an observational, real world, non-interventional study in the naturalistic setting of routine or typical clinical practice, no payment will be made to you (subject) for participation in this study. Generally, compensation also does not apply to such studies.

VIII. Right to withdraw from the study:

Participation in this study is entirely voluntary and you have the right to withdraw your participation from the study at any point of time during study period. If you decide to withdraw, it will neither affect the quality of care or the relationship with your treating physician and the nursing team.

IX. Subjects Responsibilities

You will be responsible to comply with the instruction of your treating physician. You will be solely responsible for your participation in the clinical study.

X. Contact for further information:

Thank you for taking time to read (or have read to you) the information about this study. Before you sign this document, you may ask questions about anything that you do not understand. The study staff will answer questions before, during & after the study.

Contact Details of Principal Investigator:

Contact Details of Ethics Committee: _____

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Informed Consent Form

Study Title: LONGITUDINAL ASSESSMENT OF ELECTROCARDIOGRAPHIC ABNORMALITIES IN OUT PATIENTS AT HIGH CARDIOVASCULAR RISK USING PORTABLE ECG DEVICE

Subjects No.: _____ Subject's Initials: _____

Subject's Name: _____

Date of Birth/Age: _____

Address of the Subject: _____

_____

Occupation: _____

Qualification of Subject: _____ Annual Income of Subject: _____

Sr. No.	Particulars	Initials
1	I confirm that I have read and understood the information provided to me regarding the study and have had the opportunity to ask questions.	
2	I understand that my participation in the study is voluntary and that I am free to withdraw at any time during study period, without giving any reason, without my medical care or legal rights being affected.	
3	I understand that the Sponsor of the clinical study, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw myself from the study. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published.	
4	I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s).	
5	I agree to take part in all the investigation as per the study. I agree to be a part of portable/handheld electrocardiography procedure throughout the study duration.	
6	I agree to take part in the above study.	

Signature of Subject _____

Signatory's Name: _____

Date: _____/_____/_____

Signature of the Investigator: _____

Date: _____/_____/_____

Study Investigator's Name: _____