INFORMED CONSENT DOCUMENT (ICD) PART-1

PATIENT / PARTICIPANT INFORMATION SHEET (PIS)

Title of the project:
Novel Echocardiographic Calcification Score as a Predictor of 30-Day Major Adverse Cardiovascular Events in Acute STEMI Patients: A Prospective Observational Study

INFORMATION FOR PARTICIPANTS OF THE STUDY

Purpose of this study: You are being invited to participate in this research study because you have been diagnosed with an acute ST-elevation myocardial infarction (STEMI) or Major Heart Attack. The purpose of this study is to determine whether a novel echocardiographic method—called the Echocardiographic Calcium Score (echo-CCS)—can predict major heart-related complications within 30 days of your heart attack. These complications may include death, heart failure, another heart attack, or the need for another heart procedure.

Procedure of the study: As a participant, your medical history and details of your treatment will be recorded. Post treatment completion, you'll undergo a standard echocardiography (ultrasound of the heart), where your heart will be evaluated for calcium deposits using a novel Echocardiographic Calcium Score (also known as the Hirschberg score). You will then be followed up once by phone 30 days after discharge to check if you experienced any complications.

Expected duration of the subject participation: You or your attender will be interviewed for a maximum of 10 minutes with regards to your medical history and one phone follow up 30 days after discharge

The benefits to be expected from the research to the participant: While you may not benefit directly, the findings from this study could help doctors better identify patients at higher risk of complications following a major heart attack, allowing for improved care in the future.

Any risks expected from the study to the participant: No additional risks are expected. The echocardiogram is non-invasive and part of standard cardiac evaluation.

Maintenance of confidentiality of records: All your personal information will be kept strictly confidential. Your identity will not be revealed in any reports or publications from this study. Data will be stored securely and preserved for up to three years. At any point of the study, you may withdraw from the study and subsequently data collected for study purposes will be permanently deleted.

Provision of free treatment for research related injury: No major injury is expected from study. In case of research related injury, free treatment will be provided to you as per protocol.

Reimbursement for participating in the study: We will not be able to provide reimbursement for participating in this study

Compensation to the participants for foreseeable risks and unforeseeable risks related to research study leading to disability or death: If you suffer any injury or harm related to the research, compensation will be provided according to Institute norms and ICMR guidelines.

Freedom to withdraw from the study at any time during the study period without the loss of benefits that the participant would otherwise be entitled: You are free to withdraw from the study at any time during the study period without assigning any reason and without loss of any benefit to which you are otherwise entitled.

Possible current and future uses of the biological material to be generated from the research and if the material is likely to be used for secondary purposes or would be shared with others: None

Possible current and future uses of the data to be generated from the research and if the data is likely to be used for secondary purposes or would be shared with others: The research data obtained from this study may be used for scientific purposes in the form of presentations in conferences and journal publications without revealing the identity of participants.

Address and mobile number of the Student Researcher and Guide:

Name & contact details of the Principal Investigator / Student Researcher:	**Name & contact details of Guide / Co-investigator:**
Student Name	**Guide Details:**
MBBS 5rd semester	Name of Guide
Phone Number	Designation of Guide
Email ID	Department: Cardiology
	Phone Number of Guide
	Email ID of Guide

Signature of the participant **Signature of the investigator**

Date:

INFORMED CONSENT DOCUMENT (ICD) PART-2

INFORMED CONSENT FORM

Title of the project: **Novel Echocardiographic Calcification Score as a Predictor of 30-Day Major Adverse Cardiovascular Events in Acute STEMI Patients: A Prospective Observational Study**

Participant's name:

Address:

The details of the study have been provided to me in writing and explained to me in my own language. I confirm that I have understood the above study and had the opportunity to ask questions. I confirm that I have understood about the compensation and the risks and benefits involved in this research. I understand that my participation in the study is voluntary and that I am free to withdraw at any time without giving any reason, and without my routine medical care in this hospital being affected. I understand that confidentiality of my identity will be maintained during the research period, after its completion as well as during publication of the results. Only investigator, ethics committee, institutional or regulatory authorities may have access to my information when required.

I also consent to be contacted over phone for study purposes.

I have been given a copy of information sheet giving details of the study. I volunteer to participate in the above-mentioned study.

Name and Signature/thumb impression of the participant: _____ Date: _____

Signature of the witness with date: _____ Date: _____

Name and address of the witness for illiterate participants:

Signature of the investigator with date: _____ Date: _____