



MEDILINK ETHICS COMMITTEE

1st Floor, Medilink Hospital, Nr. Shyamal Cross Road,
132 ft. Ring Road, Satellite, Ahmedabad-380 015.
M : 7069006066, E-mail : medilinkiec@yahoo.com



National Accreditation Board for Hospitals & Healthcare Providers
CERTIFICATE OF ACCREDITATION Medilink Ethics Committee, Medilink Hospital

ECR / 344 / Inst / GJ / 2013 / RR-16 / RR-19
OHRP : IRB00008578

Date: 25 April 2024

To,

PI Name: Dr. Jamshed Dalal

Institute Name: Kokilaben Dhirubhai Ambani Hospital, Mumbai.

Joint PI Name: Dr. Jay.M.Shah

Address: Krish Heart Care,
Gujarat Superspeciality Clinic,
Ahmedabad.

Reference: I) Your Submission letter dated 05 Mar 2024

II) In continuation of earlier approval letter Dated: 25 April 2023

Protocol Title:	LONGITUDINAL ASSESSMENT OF ELECTROCARDIOGRAPHIC ABNORMALITIES IN OUT PATIENTS AT HIGH CARDIOVASCULAR RISK USING PORTABLE ECG DEVICE.
Protocol No.	ERIS/OS/24/002

Subject: Approval letter of submitted documents

Dear Dr. Dr. Jamshed Dalal and Joint Dr. Jay.M.Shah

The Medilink Ethics Committee has reviewed & discussed proposed study related documents in its meeting held on **09 Mar 2024 at 05:30 p.m.** at Medilink Hospital Research Centre, 1st Floor Medilink Hospital, Near Shyamal Cross Road, 132 ft. Ring Road, Satellite, Ahmedabad-380015

Following documents were reviewed & discussed during the meeting



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Sr.No.	Documents	Version and Date
1.	Informed Consent Document	NA
2.	Data Capture Form	00_January 2022
3.	Protocol	00_January 2022

Along with all above mentioned documents were examined, reviewed and discussed.

Following Members of Medilink Ethics Committee were present on the day of the meeting **09 Mar 2024** at Medilink Hospital Research Centre, 1st Floor Medilink Hospital, Near Shyamal Cross Road, 132 ft. Ring Road, Satellite, Ahmedabad-380015.

SR. NO	NAME OF MEMBER	QUALIFICATION	ROLE IN MEC	SIGN
1.	Dr. Sadhana Kothari	MD, Pathology	Chairperson	
2.	Dr. Nitu Patodi	BHMS	Member Secretary	
3.	Dr. Adarshjit Singh	MD,DM,DNB, Pharmacology	Basic Medical Scientist	
4.	Dr. Ashok Khatri	MD (Medicine)	Clinician	
5.	Mr. Harsheel Shukla	B.Com. LLM	Legal Expert.	
6.	Mrs. Vandatta Desai	B.Com.(Hons)	Lay Person /Non Scientific Person.	
7.	Mrs. Mayaben Raol	S.S.C	Social Scientist ,Non-Governmental Voluntary	



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We approve the trial to be conducted in its presented form.

The members of the committee who participated in the voting/decision making procedure of the Committees do not have any conflict of interest in the referenced study.

This is also to confirm that neither you nor your study team members were present/Participated during Decision making Process.

The Medilink Ethics Committee expects to be informed about the:

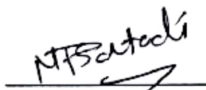
1. Progress of the study
2. Any serious adverse events occurring during the course of the study
3. Any changes in the Protocol, Patient Information Sheet & Informed Consent Form
4. Copy of final study close out report

Validity of Protocol Approval will be one year i.e. from **25 April 2024 to 24 April 2025**.

Statement of compliance:

The Medilink Ethics Committee is working in compliance with ICMR guidelines, ICH-GCP guidelines, New Drug and CT Rules, 2019 and applicable local laws.

Regards,


Dr. Nitu.Patodi

MEMBER SECRETARY
Medilink Ethics Committee,
1st Floor Medilink Hospital,
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Satellite, Ahmedabad-15
E Mail: medilinkiec@yahoo.com

09/03/24

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