



# SANGINI HOSPITAL ETHICS COMMITTEE

C/o Sangini Hospital, First Floor, Santorini Square, B/h Abhishree Complex,  
Opp. Star Bazar, Nr. Jodhpur Cross Roads, Satellite, Ahmedabad-380015,  
Gujarat, India .  
Phone number: 079 40056171 E-mail ID : sanginihospitalec@gmail.com

## Notification of Decision of IEC/IRB

Date: 08 JUN 2020

To,

Dr Rahul Trimukhe  
Interventional Cardiologist (Consultant),  
Atma Malik Hospital, Shirdi Kopargaon road,  
Post - Jeur Kumbhari, Tal, Kopargaon, Maharashtra 423601

Protocol Title: EverPro-REGISTRY: To Determine safety and performance of Everpro Everolimus-Eluting Coronary Stent System (EES) in all-comer patients with coronary artery disease (CAD) in one year follow-Up Period.

Protocol No.: EVE/01/06/2019

Dear Dr. Rahul Trimukhe

The meeting of Sangini Hospital Ethics Committee was held via **Zoom Cloud Meeting/Virtual meeting to observe the Social Distancing Norms as per the ICMR guidelines during Covid-19 Pandemic scheduled by Sangini Hospital Ethics Committee on 04 JUN 2020 at 11:00 a.m.** to review and discuss on your application to conduct above reference study.

The following documents were reviewed:

1. Study Protocol
2. Data Collection Sheet

Total 09 members attended the meeting virtually and list of members who attended and voted in the meeting is as follows:

Name	Qualification	Designation/ Role of Member in Ethics Committee
Dr. Bashir Ahmadi	M.D.(Medicine)	Chairperson
Dr. Atish Shah	M.D.(Pediatrics)	Member Secretary
Dr. Maitri Shah	M.D.(Dermatology, Venereology & Leprosy)	Clinician

Protocol No. EVE/01/06/2019

Page 1 of 3



Registered at DHHS and OHRP, Registration No. : IORG0007258, IRB00008709  
Registered at DCGI, Registration No. : ECR/147/Inst/GJ/2013  
Re-Registered at DCGI with Re-Registration No.: ECR/147/Inst/GJ/2013/RR-19



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Dr.Janak Khambholja	M.D.,DNB (Medicine)	Clinician
Dr.Sabera Mansuri	M. D.(Pharmacology)	Basic Medical Scientist
Dr. Palak Shah	M. Pharm. (Industrial Pharmacology), Ph. D (Pharm. Sciences)	Scientific Member
Ms.Sejal Sutaria	B.Com, LLB	Legal Expert
Mr.Meet Jatakia	B.E.(Computer)	Social Scientist
Mrs. Shilpa Dhankecha	B.A.(Hindi)	Lay Person

### Comments:

Dr.Kiran Prajapati MD, DM Cardiologist from White Lily Cardiology Clinic, Ahmedabad was invited as an expert.His opinion was considered but he was not a part of voting/decision making process during the meeting.

Investigational Product/Device should not be administered in the study as being the observational retrospective study.

Patient authorization must be taken from the patient for using their data for the publication

Neither you nor any of your study team member(s) participated in voting/ decision making process during the meeting.

### Type of review:

- New Review  
 Revised Review  
 Expedited Review

### Review outcome:

- Approval  
 Request for modification or information  
 Disapproval  
 Termination/suspension of the research proposal/ongoing study

Protocol No. EVE/01/06/2019



Page 2 of 3

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## Remarks/ Suggestions:

The IEC/IRB hereby approves the research proposal to be conducted in its presented form only. The validity of decision of IEC/IRB will be of one (01) year from the date of decision of IEC/IRB.

The IEC/IRB expects to be informed about study related information (new or changed or updated) that may affect safety of subjects and/or conduct of the study.

The IEC/IRB expects to be informed about the progress of the study at least once in a year from date of decision of IEC/IRB and/or case-by-case basis for pharmacodynamic study, pharmacokinetic study, epidemiological study, COHORT study, BA/BE study etc.

Member of IEC/IRB will have right to monitor study site and conduct of study with prior intimation.

Notification letters regarding initiation, on-going and completion of study should be informed.

The IEC/IRB operates in accordance with New Drugs and Clinical Trials Rules, 2019, ICMR Guidelines for Biomedical research on Human Subjects, ICH-GCP guidelines which govern Good Clinical Practices and IEC/IRB operations, WMA Declaration of Helsinki, Brazil, Oct 2013 and 21 CFR part 56 and 21 CFR part 50.

Yours sincerely,

Dated : 08 Jun 2020

Dr. Bashir Ahmadi  
(Chairperson)



Dr. Atish Shah  
(Member Secretary)