

## Institutional Ethics Committee approval



**KASTURBA HOSPITAL  
MANIPAL**

(An associate Hospital of MAHE, Manipal)

### **Kasturba Medical College and Kasturba Hospital Institutional Ethics Committee**

(Registration No. ECR/146/Inst/KA/2013/RR-19)

(DHR Registration No.EC/NEW/INST/2019/374)

#### **Communication of the decision of the Institutional Ethics Committee**

**Wednesday 15<sup>th</sup> July 2020**

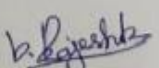
**IEC : 438/2020**

Project title	:	Role of Duplex Ultrasound in the Assessment of Arterio-Venous Fistula in Patients with Chronic Kidney Disease Stage 5.
Principal Investigator	:	Dr. Bendalam Gouthami
Co Investigators	:	Dr. Shankar Prasad, Dr. Ravindra Prabhu, Dr. Indu R Rao
Name & Address of Institution	:	Department of Nephrology, KMC, Manipal.
Status of review	:	New
Date of review	:	14.07.2020
Decision of the IEC	:	Approved with modifications for the study period from IEC approval to 10.02.2022.
IEC Approval Date	:	20 OCT 2020
Endorsement of continuation of approval : (due date 13.07.2021)	:	Signature and Seal

- The PI and all members of the project shall ensure compliance to current regulatory provisions provisions (as per NDCT rules 2019 and ICH-GCP), Ethical Guidelines for Biomedical Research on Human Participants by ICMR, and the SOP of IEC including timely submission of Interim Annual Report and Final Closure Report
- Participant Information Sheet and a copy of signed Informed Consent shall be given to every research participant
- Inform IEC in case of any proposed amendments (change in protocol / procedure, site / Investigator etc)
- Inform IEC immediately in case of any Adverse Events and Serious Adverse Events.
- Members of IEC have the right to monitor any project with prior intimation.

#### **Additional Recommendations: CTRI Registration**

- Ensure registration of this study at Clinical Trials Registry - India (CTRI) before the enrolment of the first participant The IEC to be notified about the CTRI registration within 7 days of successful registration/clearance.

  
**Dr. Rajeshkrishna Bhandary P**  
**MEMBER SECRETARY - IEC**

