

File No. EC/NEW/INST/2021/1648



सत्यमेव जयते

Government of India
Ministry of Health & Family Welfare
Department of Health Research
(National Ethics Committee Registry for Biomedical and Health Research)

2nd Floor, IRCS Building,
Red Cross Road, New Delhi – 110001
Date : 18-Apr-2024

FORM CT-03

(See rules 17 and 18)

GRANT OF REGISTRATION OF ETHICS COMMITTEE RELATING TO BIOMEDICAL HEALTH RESEARCH

Registration No. EC/NEW/INST/2024/KL/0455

The designated authority hereby registers and permits JEC AMALA INSTITUTE OF MEDICAL SCIENCES, Amala Institute of Medical Sciences Amalanagar, City-Thrissur, District-Thrissur - Kerala - 680555 Contact No.: 0487-2304000 Fax No.: to perform duties of ethics committee as specified in the New Drugs and Clinical Trials Rules, 2019.

2. The ethics committee shall observe the conditions of registration specified in Chapter IV of the New Drugs and Clinical Trials Rules, 2019 and the Drugs and Cosmetics Act, 1940.

Place : New Delhi

Date : 18-Apr-2024

ANU Digitally signed
by ANU NAGAR
Date: 2024.04.18
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Designated Registration Authority
Stamp

Betsy



Dr. BETSY THOMAS
MD, FRCOG, DNB, MICOG
PRINCIPAL
AMALA INSTITUTE OF MEDICAL SCIENCES
AMALA NAGAR, THRISSUR-680 555



File No. EC/22/000050
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Ethics Committee Registration Division)

FDA Bhawan, Kotla Road,
New Delhi - 110002, India
Dated: 25-Aug-2022

To

The Chairman
Amala IMS, Thrissur-680555
Amala Institute Of Medical Sciences, Thrissur
Amala Nagar Thrissur, 680555 Thrissur Thrissur
Kerala - 680555 India

Subject: Ethics Committee Re-Registration No. ECR/653/Inst/KL/2014/RR-22 issued under New Drugs and Clinical Trials Rules, 2019.

Sir/Madam,

Please refer to your application no. EC/RENEW/INST/2022/13655 dated 15-Feb-2022 submitted to this Directorate for the Re-Registration of Ethics Committee.

Please find enclosed registration of the Ethics Committee in Form CT-02 vide Registration No. ECR/653/Inst/KL/2014/RR-22. The said registration is subject to the conditions as mentioned below:-

Betsy

Yours faithfully



Dr. BETSY THOMAS
MD, FRCOG, DNB, MICOG
PRINCIPAL
AMALA INSTITUTE OF MEDICAL SCIENCES
AMALA NAGAR, THRISSUR-680 555

Stamp: Digitally signed by VENUGOPA...
VENUGOPA
Drugs Control General Authority
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Date: 2022.08.25 14:00:00 +05'30'

Conditions of Registration

1. The registration is valid from 25-Aug-2022 to 24-Aug-2027, unless suspended or cancelled by the Central Licensing Authority.
2. This certificate is issued to you on the basis of declaration/submission made by you.
3. Composition of the said Ethics Committee is as per the Annexure.
4. No clinical trial or bioavailability or bioequivalence protocol and related documents shall be reviewed by an Ethics Committee in meeting unless at least five of its members as detailed below are present in the meeting, namely:-
 - (i) medical scientist (preferably a pharmacologist);
 - (ii) clinician;
 - (iii) legal expert;
 - (iv) social scientist or representative of non-governmental voluntary agency or philosopher or ethicist or theologian or a similar person;
 - (v) lay person.
5. The Ethics Committee shall have a minimum of seven and maximum of fifteen members from medical.