



File No. EC/20/000358
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: 15-Oct-2020

To

The Chairman
Ethics Committee of MCE Society
Maharashtra Cosmopolitan Education MCE Society
Research Cell IInd Floor MARDC
M A Rangoonwala College of Dental Sciences & Research Centre
2390-B, KB Hidayatullah Road, Azam Campus Camp
Pune, Maharashtra - 411001 India

Subject: Ethics Committee Re-Registration No. ECR/511/Inst/MH/2014/RR-20 issued under New Drugs and Clinical Trials Rules, 2019.

Sir/Madam,

Please refer to your application no. EC/RENEW/INST/2020/9388 dated 28-Sep-2020 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/511/Inst/MH/2014/RR-20. The said registration is subject to the conditions as mentioned below:-

Yours faithfully

VENUGOPAL
GIRDHARILA
L SOMANI

(Dr. V.G. Somani)
Drugs Controller General (I) &
Central Licensing Authority

Conditions of Registration

1. The registration is valid from 15-Oct-2020 to 14-Oct-2025, unless suspended or cancelled by the Central Licencing 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.