



File No. EC/19/000541
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: 21-Feb-2020

To

The Chairman
Institutional Ethics Committee
Sancheti Inst for Orthopedics and Rehabilitation
16, Shivajinagar Sancheti Research Centre Pune
Pune Maharashtra - 411005 India

Subject: Ethics Committee Re-Registration No. ECR/90/Inst/MH/2013/RR-20 issued under New Drugs and Clinical Trials Rules, 2019.

Sir/Madam,

Please refer to your application no. EC/RENEW/INST/2019/6501 dated 21-Oct-2019 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/90/Inst/MH/2013/RR-20. The said registration is subject to the conditions as mentioned below:-

Yours faithfully

VG
SOMANI

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

Conditions of Registration

1. The registration is valid from 21-Feb-2020 to 20-Feb-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.
5. The Ethics Committee shall have a minimum of seven and maximum of fifteen members from medical,

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