Government of India
Ministry of Health & Family Welfare
Directorate General of Health Services
Office of Drugs Controller General (India)
Central Drugs Standard Control Organization

FDA Bhawan, Kotla Road,
New Delhi – 110 002, India
Dated: 14 02 2017

To
The Chairman
Institutional Ethics Committee
Smt. Kashibai Navale medical College and General Hospital
49/1, Off westerly Bypass Highway Narhe (Ambegaon)
Pune- 411041, Maharashtra
India


Sir/Madam,

Please refer to your application submitted to this Directorate for the Re-Registration of Ethics Committee.

Based on the documents submitted by you, this office hereby re-registers the INSTITUTIONAL ETHICS COMMITTEE situated at SMT. KASHIBAI NAVALE MEDICAL COLLEGE AND GENERAL HOSPITAL, 49/1, OFF WESTERLY BYPASS HIGHWAY NARHE (AMBEGAON), PUNE- 411041, MAHARASHTRA, INDIA with Registration Number ECR/275/Inst/MH/2013/RR-16 as per the provisions of Rule 122DD of the Drugs and Cosmetics Rules, 1945 subject to the following conditions:

1. The re-registration shall be in force from 29.04.2016 to 28.04.2019, unless it is sooner suspended or cancelled.

2. This registration is subject to the conditions specified under Rule 122DD and Appendix VIII of Schedule-Y of Drugs and Cosmetics Act, 1940 and Rules 1945.

3. The Ethics Committee shall review and accord its approval to a clinical trial at appropriate intervals as specified in Schedule Y and the Good Clinical Practice Guidelines for Clinical Trials in India and other applicable regulatory requirements for safeguarding the rights, safety and well-being of the trial subjects.

4. In the case of any serious adverse event occurring to the clinical trial subjects during the clinical trial, the Ethics Committee shall analyze and forward its opinion as per procedures specified under APPENDIX XII of Schedule Y.

5. The Ethics Committee shall allow inspectors or officials authorized by the Central Drugs Standard Control Organization to enter its premises to inspect any record, data or any document related to clinical trial and provide adequate replies to any query raised by such inspectors or officials, as the case may be, in relation to the conduct of clinical trial.

6. The licensing authority shall be informed in writing in case of any change in the membership or the constitution of the ethics committee takes place.

7. All the records of the ethics committee shall be safely maintained after the completion or termination of the study for not less than five years from the date of completion or termination of the trial (Both in hard and soft copies).

8. If the Ethics Committee fails to comply with any of the conditions of registration, the Licensing Authority may, after giving an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons therefore, suspend or cancel the registration of the Ethics Committee for such period as considered necessary.
ECR/528/Kashibhai/Inst/MH/2013/Re-Registration-2016

Ministry of Health & Family Welfare
Directorate General of Health Services
Office of Drugs Controller General (India)
Central Drugs Standard Control Organization

FDA Bhawan, Kotla Road,
New Delhi
Date: 17/02/2017

To

The Chairman,
Institutional Ethics Committee
Smt. Kashibai Navale medical College and General Hospital
49/1, Off westerly Bypass Highway Narhe (Ambegaon)
Pune- 411041, Maharashtra
India

Subject: Re-Registration of Ethics Committee under Rule 122DD (7) of the Drugs and Cosmetics Rules 1945.

Ref:

i. Registration Certificate dated 29.04.2013 granted to you.
ii. Your application for re-registration dated 16.06.2016.

You are hereby informed that you were granted registration certificate under Rule 122DD of the Drugs and Cosmetics Rules 1945 vide ref(i) which was valid until 29.04.2016.

As per Rule 122DD (7), the application for re-registration shall be received by the Licensing Authority within 3 months before expiry. However your application vide ref (ii) was received by this Directorate on 29.06.2016, which is much beyond the stipulated time line.

Keeping in view of the requirements for continuous monitoring of the clinical trials approved by your Ethics Committee under the provisions of the Drugs and Cosmetics Rules, Schedule Y read with GCP, your Ethics Committee is hereby re-registered for the period 29.04.2016 to 28.04.2019 with a directive that the same shall not be repeated in future. Any future delayed submissions/non-compliances will be viewed seriously.

[Signature]
Joint Drugs Controller (I)
Licensing Authority

[Stamp]