File No. ECR/92/IPGME&R/Inst/WB/2013

From:

The Drugs Controller General (India)
Directorate General of Health Services

FDA Bhawan, Kotla Road,
New Delhi – 110 002
Dated: 05 APR 2013

To

The Chairperson
IPGME&R Research Oversight Committee
Office of the Dean, College Building, 5th Floor,
Institute of Post graduate Medical Education & Research
244 Acharya J. C. Bose Road, Kolkata - 700020

SUB: - Ethics Committee Registration No. **ECR/35/Inst/WB/2013** issued under Rule 122DD of the Drugs & Cosmetics Rules1945.

Dear Sir

Please refer to your application no. Inst/IEC/270, dated 14/03/2013, Fts no. 16739/2013 dated 18/03/2013 submitted to this office for the Registration of Ethics Committee.

Based on the documents submitted by you, this office hereby Registers the **IPGME&R Research Oversight Committee (Institutional Ethics Committee for research involving human subjects)** situated at **Office of the Dean, College Building, 5th Floor, Institute of Post graduate Medical Education & Research, 244 Acharya J. C. Bose Road, Kolkata - 700020** with Registration number **ECR/35/Inst/WB/2013** as per the provisions of Rule 122DD of the Drugs and Cosmetics Rules, 1945 subject to the following conditions:

1. 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.
2. 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.
3. In the case of any serious adverse event occurring to the clinical trial subjects during the clinical trial, the Ethics Committee shall analyse and forward its opinion as per procedures specified under APPENDIX XII of Schedule Y.
4. The Ethics Committee shall allow inspectors or officials authorised 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.
5. 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.
6. 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).
7. 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.
8. This registration shall be in force for a period of three years from the date of issue, unless it is sooner suspended or cancelled.

Yours Faithfully

(Dr. G.N. Singh)
Drugs Controller General (I) & Licensing Authority