File No. ECR/1260/AIIMS/Inst/UK/2015

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: 14/05/2015

To

The Chairman,
Institute Ethics Committee,
All India Institute of Medical Sciences,
Department of Physiology,
Veerbhadra Marg, Rishikesh, Uttrakhand-249201,
India.

SUB: - Ethics Committee Registration No. **ECR/736/Inst/UK/2015** issued under Rule 122DD of the Drugs & Cosmetics Rules1945.

Sir/Madam,

Please refer to your application no. aims/iec/15/94 dated 24.01.2015 and your response dated 20.04.2015 submitted to this office for the Registration of Ethics Committee.

Based on the documents submitted by you, this office hereby registers the **INSTITUTE ETHICS COMMITTEE, ALL INDIA INSTITUTE OF MEDICAL SCIENCES** situated at **DEPARTMENT OF PHYSIOLOGY, VEERBHADRA MARG, RISHIKESH, UTTRAKHAND-249201, INDIA** with Registration number **ECR/736/Inst/UK/2015** 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 analyze and forward its opinion as per procedures specified under APPENDIX XII of Schedule Y.
4. 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.
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).