To

The Chairman
Scientific Research and Ethical Review Committee (SRERC)
Department of Laboratory Medicine
Batra Hospital & Medical Research Centre
1, Tuglakabad Institutional Area, M.B. Road
New Delhi- 110062, 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 SCIENTIFIC RESEARCH AND ETHICAL REVIEW COMMITTEE (SRERC) situated at DEPARTMENT OF LABORATORY MEDICINE, BATRA HOSPITAL & MEDICAL RESEARCH CENTRE 1, TUGLAKABAD INSTITUTIONAL AREA, M.B. ROAD, NEW DELHI- 110062, INDIA with Re-Registration Number ECR/295/Inst/DL/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 01.05.2016 to 30.04.2019, 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.
its members, who is from outside the institute, shall be appointed as chairman, one member as a Member,
Secretary and rest of the members shall be from Medical, Scientific, Non-Medical and Non-scientific fields
including lay public.

10. The committee shall include at least one member whose primary area of interest or specialization is Non-
scientific and at least one member who is independent of the institution besides; there should be appropriate
gender representation on the Ethics Committee.

11. The Ethics committee can have as its members, individuals from other Institutions or Communities, if required.

12. Members should be conversant with the provisions of clinical trials under this Schedule, Good Clinical Practice
Guidelines for clinical trials in India and other regulatory requirements to safeguard the rights, safety and well-
being of the trial subjects.

13. For review of each protocol the quorum of Ethics Committee shall be at least five members with the following
representations:

I. Basic medical scientist (preferably one 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 from community

14. The members representing medical scientist and clinicians should have Post graduate qualification and adequate
experience in their respective fields and aware of their role and responsibilities as committee members.

15. As far as possible, based on the requirement of research area such as HIV, Genetic disorder, etc., specific
patient group may also be represented in the Ethics Committee.

16. There should be no conflict of interest. The members shall voluntarily withdraw from the Ethics Committee
meeting while making a decision on an application which evokes a conflict of interest which may be indicated
in writing to the Chairman prior to the review and be recorded so in the minutes. All members shall sign a
declaration on conflict of interest.

17. Subject experts or other experts may be invited to the meetings for their advice. But no such expert shall have
voting rights.

18. This certificate is issued to you on the basis of declaration/submission by you that yours is an Institution and re-
registration is sought for Institutional Ethics Committee.

19. Funding mechanism for the Ethics Committee to support their operations should be designed to ensure that the
committee and their members have no financial incentive to approve or reject particular studies.

20. SOP’s for funding of the Ethics committee in order to support their operations must be maintained. The records
of income & expenditure of Ethics Committee shall be maintained for review and inspection.

21. The Chairman of Ethics Committee shall enter into MOU with head of institution, that necessary support and
facilities and independence will be provided to Ethics Committee and their records will be maintained as long
as required.

22. Ethics Committee may undertake the review and monitoring of clinical trial protocols of other investigator(s)
and site(s) who do not have their IEC, subject to the condition that the other sites are within the loco-
regional and community settings similar to that of the registered Ethics committee. The approving ethics
committee must be willing to accept their responsibilities for the study at such trial site(s) and the trial site(s) willing to
accept such an arrangement.

23. Ethics Committee shall review and approve the suitability of the investigator and trial site for the proposed trial.
The ethics committee shall undertake proper causality assessment of SAE’s with the help of subject experts
where required, for deciding relatedness and compensation, as per condition no (4) mentioned above.

Joint Drugs Controller, (I) & Licensing Authority

(Dr. V.G. Somani)
Directorate General of Health Services
FOA Bhawan, Kotla Road, New Delhi-110002

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