

ECR/1145/ERA/Inst/UP/2014/Re-Registration-2018



Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Ethics Committee Registration Division)

FDA Bhawan, Kotla Road,
New Delhi – 110 002, India
Dated: 26/06/2019

To

The Chairman
Institutional Ethics Committee,
Era's Luchnow Medical College & Hospital,
Sarfarazganj, Hardoi Road,
Lucknow-226003, Uttar Pradesh, India.

Sub: - Ethics Committee Re-Registration No. **ECR/717/Inst/UP/2015/RR-18** issued under Rule 122DD of the Drugs & Cosmetics Rules, 1945.

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 **ERA'S LUCHNOW MEDICAL COLLEGE & HOSPITAL, SARFARAZGANJ, HARDOI ROAD, LUCKNOW-226003, UTTAR PRADESH, INDIA** with Re-Registration Number **ECR/717/Inst/UP/2015/RR-18** 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 12.03.2018 to 11.03.2021, unless it is sooner suspended or cancelled.
2. This Registration is subject to the conditions specified under the New Drugs & Clinical Trials Rules, 2019.
3. The Ethics Committee shall review and accord its approval to a clinical trial and also carry ongoing review of the trial at appropriate intervals as specified in Chapter III of the New Drugs & Clinical Trials Rules, 2019 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 Chapter VI of the New Drugs & Clinical Trials Rules, 2019.
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

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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.
9. Ethics Committee shall consist of not less than seven members and is subject to a maximum of 15. One among its members, who is from outside the institute, shall be appointed as chairman, one member as a Member Secretary who is affiliated with institute or organization and rest of the members shall be from medical, scientific, non-medical and non-scientific fields including lay public, one women member.
10. The Ethics Committee shall consist of at least 50% of member who are not affiliated with institute or organization in which such committee is constituted.
11. 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.
12. The Ethics committee can have as its members, individuals from other Institutions or Communities, if required.
13. Members should be conversant with the provisions under New Drugs & Clinical Trials Rules, 2019, 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.
14. 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
15. 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.
16. 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.

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17. 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.
18. Subject experts or other experts may be invited to the meetings for their advice. But no such expert shall have voting rights.
19. 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.
20. 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.
21. 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.
22. 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.
23. 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.
24. 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.

Yours faithfully,



(Dr. S. Eswara Reddy)

Drugs Controller General (I) & Licensing Authority

Dr. S. ESWARA REDDY
Drugs Controller General (India)
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