

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: 17/04/2017

To

The Chairman  
Institutional Ethics Committee  
VSPM Dental College & Research Centre  
Digdoh Hills, Hingna Road, Nagpur-440019  
Maharashtra, India

Sub: - Ethics Committee Registration No. ECR/885/Inst/MH/2017 issued under Rule 122DD of the Drugs & Cosmetics Rules 1945.


Sir/Madam,

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

Based on the documents submitted by you, this office hereby registers the **INSTITUTIONAL ETHICS COMMITTEE**, situated at **VSPM DENTAL COLLEGE & RESEARCH CENTRE, DIGDOH HILLS, HINGNA ROAD, NAGPUR-440019, MAHARASHTRA, INDIA** with Registration number **ECR/885/Inst/MH/2017** 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).
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 therefor, 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.

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 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 registration is sought for Institutional Ethics Committee.
19. Funding mechanisms for the Ethics Committee to support their operations should be designed to ensure that the committees 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 (3) mentioned above.

  
(Dr. G. N. Singh)

Drugs Controller General (I) & Licensing Authority

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## **Institutional Ethics Committee, VSPM'S Dental College and Research Centre, Nagpur**

The Institutional Ethics Committee (IEC) was formed in 2008.

The constitution of IEC is as per ICMR guidelines.

IEC is registered with Central Drugs Standard Control Organization, Director General of Health Services, Ministry of Health and Family Welfare, Government of India with registration no ECR/885/Inst/MH/2017.

### **Objectives**


IEC works with the following objectives,

1. To promote a democratic exchange of scientific and ethical values and concerns, and to critically analyze them while looking for opportunities to enhance the scientific and ethical integrity of the institution
2. To ensure competent review and appraisal of all scientific and ethical aspects of research projects received in accordance with the appropriate laws and welfare of participants.
3. Consultations for ethics in clinical research.

### **Functions**

The terms of reference for the IEC is to ensure the highest scientific and ethical standards of research at VSPMDCRC. The IEC has the following functions

1. To maintain a consistent scientific and ethical framework for patient care and research, and for integrating ethical values into practice, policy relationships, and organizational activities.
2. To review and approve proposals for clinical, basic or translational research for scientific and ethical content.
3. To improve ethical standards and issue guidelines on ethical dilemmas related to patient care services.
4. To work as a forum to advise the administration in case of any ethical issues that may arise from patients, families or public.

  
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## SOP

The objective of this SOP is to contribute to the effective functioning of the IEC at the VSPM'S Dental College and Research Centre, Nagpur so that a quality and consistent ethical review mechanism for health and biomedical research is put in place to all proposals dealt by the Committee.

IEC will review and approve all types of research proposals involving human participants with a view to safeguard the dignity, rights, safety and well being of actual or potential research participants. The goal of the research, however important, should never be permitted to override the health and well being of the research subject

The research protocol should be submitted in the prescribed format of the IEC in triplicate along with the suggested enclosures till the 7<sup>th</sup> of every month. IEC meetings are scheduled once monthly, including 2 meetings for approval of synopsis of final dissertation of first year PG students. Synopsis presentation of dissertation topics of PhD scholars also carried out before the submission to MUHS University, Nashik. Subject experts are invited to enrich and validate the research protocol whenever required. According to committee decision, all research projects in the institution are undertaken only after written approval from the IEC. It is mandatory that all research projects by staff, PhD scholars, PG, UG students and interns should be approved by the IEC. The principal investigator of the research project has to give brief audio-visual presentation of the research project. Certificate of the approval of the research project is issued to the principal investigator. The ongoing research projects are reviewed at regular intervals. The principal investigator has to provide a justification if the research project is not completed in the time period mentioned in the synopsis. All research documents are preserved for a minimum of 5 years after completion of the study. A completed report of the research project has to be submitted to the IEC of all completed research projects in the departments.

The IEC will take care that all the cardinal principles of research ethics viz. Autonomy, Beneficence, Non-maleficence and Justice. For this purpose, it will look into the aspect of informed consent process, risk benefit ratio, distribution of burden and benefit and provisions for appropriate compensation whatever required. It will review the proposals before start of the studies as well as monitor the research throughout the study until and after completion by examining the annual report and final reports. The committee will also examine whether all regulatory requirements and laws are complied with or not. Institutional ethics committee of Dental College and Research Centre, Nagpur functions as per Schedule 'Y' & ICH & GCP (International Council of Harmonization and Good Clinical Practices) guide lines

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