

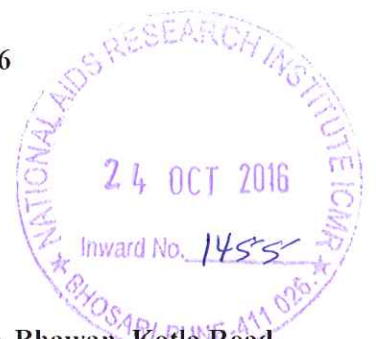
Shahabuddin  
for DDA  
24.10.16

ECR/63/NARI/INST/MH/2013-Re-Registration-2016



सत्यमेव जयते

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: 17.10.2016

To

The Chairman,  
Institutional Ethics Committee,  
National AIDS Research Institute (ICMR), Pune,  
73, G Block, MIDC, Bhosari, Pune-411026,  
Maharashtra, India.

**SUB:** - Ethics Committee Re-Registration No. ECR/23/INST/MH/2013/RR -16 issued under Rule 122DD of the Drugs & Cosmetics Rules 1945.

Sir/Madam,

Please refer to your application no NARI/RRG/16-17/73 dated 05.08.2016 submitted to this office 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 **NATIONAL AIDS RESEARCH INSTITUTE (ICMR), PUNE, 73, G BLOCK, MIDC, BHOSARI, PUNE-411026, MAHARASHTRA, INDIA** with Registration Number **ECR/23/INST/MH/2013/RR -16** as per the provisions of Rule 122DD of the Drugs and Cosmetics Rules, 1945 subject to the following conditions:

1. The registration shall be in force from 02.04.2016 to 01.04.2019, 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.
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 re-registration is sought for Institutional Ethics Committee.

*V. G. Somani*

(Dr. V. G. Somani)  
Joint Drugs Controller (I) & Licensing Authority

**Dr. V. G. SOMANI**  
Joint Drugs Controller (India)  
Directorate General of Health Services  
F-1, Anawan, Kofia Road, New Delhi-110002



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Ministry of Health & Family Welfare  
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Please refer to your application no. NARI/RRG/16-17/73 dated 05.08.2016 submitted to this office for the Re-Registration of Ethics Committee.

Your Ethics Committee is hereby re-registered under Rule 122DD vide Registration No. ECR/23/INST/MH/2013/RR -16 with the following composition and all the condition mentioned under the Registration certificate issued to you.

Sr. No.	Name of member	Qualification	Role/Designation in Ethics Committee
1.	Dr. V.S. Padbidri	MBBS, P.hD	Chairman
2.	Dr. Raman Gangakhedkar	MBBS, DCH, MPH	Member Secretary
3.	Dr. Aparna Shrotri	MD, DGO	Clinician
4.	Dr. A.L. Kakrani	MD (Medicine)	Clinician
5.	Dr. Mohan D. Gupte	MBBS, DPH, MD (Preventive Social Medicine)	Clinician
6.	Dr. Vijaya Pandit	MBBS, MD (Pharmacology)	Basic Medical Scientist
7.	Dr. Pratibha Worlikar	MD (Pharmacology)	Basic Medical Scientist
8.	Mrs. Varsha Chinchkar	BA	Lay Person
9.	Dr. Jaya Sagade	LLB, LLM, PhD	Legal Expert
10.	Justice Srikanth R. Santhe		Legal Expert
11.	Mrs. Nirmala Hiremath	BA, MSW	Social Scientist
12.	Mrs. Madhuri Abhyankar	MSW	Social Scientist
13.	Prof. Jayanta K.Pal	M.Sc (Zoology), PhD (Biotechnology)	Scientific Member
14.	Manisha Pawar	SSC	Non Scientific Member

(Dr. V. G. Somani)

Joint Drugs Controller (I) & Licensing Authority

**Dr. V. G. SOMANI**  
Joint Drugs Controller (I)  
Directorate General of Health Services  
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