

ECR/1760/Believers/Inst/KL
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: 25/06/2018

To

The Chairman
Institutional Ethics Committee
Believers Church Medical College Hospital
P.O. Box 31, St. Thomas Nagar, Kuttapuzha
Thiruvalla- 689103, Kerala, India

Sub: - Ethics Committee Registration No. ECR/1098/Inst/KL/2018 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 **BELIEVERS CHURCH MEDICAL COLLEGE HOSPITAL, P.O. BOX 31, ST. THOMAS NAGAR, KUTTAPUZHA, THIRUVALLA- 689103, KERALA INDIA** with Registration number **ECR/1098/Inst/KL/2018** 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 and also carry ongoing review of the 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. Provided that if the application for re-registration is received by the Licensing Authority within three months before the expiry, the registration shall continue to be in force until orders are passed by the said authority.
 - a. 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.

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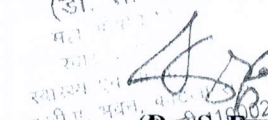
Sir/Madam,

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

Your Ethics Committee is hereby registered under Rule 122DD vide Registration No. **ECR/1098/Inst/KL/2018** 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. Tomy Philip	MD (General Medicine)	Chairman
2.	Dr. Satish Thomas	MD (Ophthalmology)	Member Secretary
3.	Dr. Anna Mani	MD (General Medicine)	Clinician
4.	Dr. Vinoo Jacob	MBBS, FRCS	Clinician
5.	Dr. Kannan Vaidyanathan	MD (Biochemistry)	Basic Medical Scientist
6.	Adv. Joseph John	LLB	Legal Expert
7.	Adv. Princy Joseph	LLB	Legal Expert
8.	Mr. P.O. Mathew	MA	Lay Person
9.	Rev. Varghese Abraham	BA, BD, Dmin	Theologian

(डॉ. स. ईश्वर रेड्डी) Yours faithfully,


(Dr. S. Eswara Reddy)
Drugs Controller General (I) & Licensing Authority