

EMMANUEL HOSPITAL ASSOCIATION

808/92 DEEPALI BUILDING, NEHRU PLACE, NEW DELHI - 110019

Tel.: 011-30882008/09 | Fax: 011-30882019 | email: centraloffice@eha-health.org | web: www.eha-health.org



INSTITUTIONAL ETHICS COMMITTEE

Certificate of Approval

Dr. Jacob Puliyel <i>Chairman</i>	Title: Parenting for life long health: Assessing the feasibility, acceptability, implementation aspects and outcomes of an adapted parenting course for parents in North India.
Mr. Siju Thomas <i>Member (Legal)</i>	Researchers: Dr. Pratibha Esther Singh, Ms. Pooja Pillai, Mr. Somesh Pratap Singh.
Ms. Sharmila Banerjee Livingston <i>Member</i>	Protocol No: 191
Dr. Oomen John <i>Member</i>	Comment:
Dr. Savita Doeme <i>Member</i>	The study on "Parenting for life long health: Assessing the feasibility, acceptability, implementation aspects and outcomes of an adapted parenting course for parents in North India" was reviewed at the EHA IEC meeting on the 8 th of November 2018. It was reviewed again on the 3 rd of January, 2019.
Dr. Jameela George <i>Member Secretary</i>	The protocol with clarification given was approved.
	<i>The protocols are circulated to all members of the ethics committee prior to the scheduled meeting.</i>

Approval is subject to the following conditions:

It is the principal investigators' responsibility to ensure that all researchers associated with this project are aware of the conditions of approval and which documents have been approved.

All Serious adverse effects have to be informed to the Secretary of the Institutional Ethics Committees per Good Clinical Practice (GCP) within 7 days. This approval stands automatically revoked if this is not complied with.

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Furthermore the principal investigator is required to notify the Secretary of the Institutional Ethics Committee the following:

1. Any significant change to the project and the reason for that change, including an indication of ethical implications (if any).
2. A delay of more than 12 months in the commencement of the project.
3. The inability of the principal researcher to continue in that role.
4. Any expiry of the insurance coverage provided with respect to sponsored clinical trials and proof of re-insurance;
5. Any unforeseen events or unexpected developments that could materially affect the approval
6. The Ethics Committee may conduct an audit/intermediate analysis if found necessary. All required data/documents must be provided to the Committee before further recruitment of cases;
7. Termination or closure of the project.

Additionally, the principal researcher/investigator is required to submit

- A Progress Report every 12 months for the duration of the project;
- A request for extension of the project prior to the expiry date, if applicable; and,
- A detailed Final Report at the conclusion of the project.

All research subject to the EHA Institutional Ethics Committee review must be conducted in accordance with the Ethical Guidelines for Biomedical Research on Human Participants published by Indian Council of Medical Research (ICMR).

Special conditions: None

Signed:.....*Janeh George*.....

Member Secretary IEC

(Please quote project no. and title in all correspondence)

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