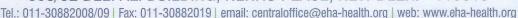
EMMANUEL HOSPITAL ASSOCIATION

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





INSTITUTIONAL ETHICS COMMITTEE

Certificate of Approval

Dr. Jacob Puliyel *Chairman*

Research Title: Evaluating the feasibility, implementation and effectiveness of Nae Disha -3 (youth resilience and mental health intervention) in diverse school settings

Mr. Siju Thomas
Member (Legal)

Protocol No. 224

Ms. Sharmila Banerjee Livingston Researcher: Ms. Pillai Pooja S

Member

Location: Burans, Dehradun

Dr. Oomen John Member

Comments:

Dr. Savita Duomai Member Thank you for submitting the above-mentioned research for the EHA Institutional Ethics Committee approval. EHA IEC members reviewed the proposal in the committee meeting held on 04.03.2020. The clarification you•have provided for the issue raised by the committee has been satisfactory.

Ms. Imtimnela Aier
Member

Version 2 of the proposal has been approved by the committee to carry out the study.

Dr. Jameela George Member Secretary

The committee wishes you and your team success in these endeavors.

Approval is subject to the following conditions:

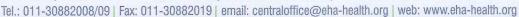
It is the principal investigators' responsibility to ensure that all researchers associated with this project are aware of the conditions of approval and which documents have been approved.

All Serious adverse effects have to be informed to the Secretary of the Institutional Ethics Committee as 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 <u>Final Report</u> 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

Member Secretary, IEC

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

