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

FELLOWSHIP FOR TRANSFORMATION THROUGH CARING

# INSTITUTIONAL ETHICS COMMITTEE

## Certificate of Approval

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|---|---|
| Dr. Jacob Puliyel *Chairman*<br><br>Mr. Siju Thomas *Member (Legal)*<br><br>Ms. Sharmila Banerjee Livingston *Member*<br><br>Dr. Oomen John *Member*<br><br>Dr. Savita Duomai *Member*<br><br>Ms. Imtimnela Aier *Member*<br><br>Dr. Jameela George *Member Secretary* | **Research Title:** "Examining an intervention to improve the mental health of female carers of persons with disability and mental health issues in the Covid crisis -a pre-post study in urban Uttarakhand"<br><br>**Protocol No:** 240<br><br>**Location:** Dehradun<br><br>**Researchers**: Pooja S Pillai<br><br>***Comments:***<br><br>The research proposal is well written and clear, to test the effectiveness of an existing intervention during the pandemic related circumstances.<br><br>**Review outcome:**<br><br>Version 2 of the protocol with the revised title, methodology and tools for qualitative data collection has been approved.<br><br>*This proposal was reviewed during the lockdown period of COVID 19*<br>*The committee meeting was held using MS Teams* |

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 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: Jamuna George 4.8.2020

Member Secretary, IEC

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