



Ethics Committee for Academic Research Projects (ECARP)
PG Academic Committee, T.N. Medical College & BYL Nair Hospital
CDSCO Registration No. ECR/465/Inst.MH/2013/RR-19

ECARP Approval Letter

Date: 27th May 2020

ECARP Reference No: ECARP/ 2020/63

To,
Dr. Niraj Mahajan
Department of Obstetrics & Gynaecology
TN Medical College & BYL Nair Ch. Hospital
Mumbai Central, Mumbai 400 008

Ref: Project no. ECARP/2020/63 entitled "**National Registry of Pregnant women with COVID-19 in India - PregCovid study**".

Dear Dr. Mahajan,

In view of the current COVID-19 pandemic situation and lockdown in Mumbai, a virtual conference meeting of the Ethics Committee for Academic Research Projects (ECARP), TN Medical College & BYL Nair Hospital was held on 27th May 2020 at 12.30 pm with Dr. Vasumathi Divekar as the Chairperson. The following members voted for the project.

Sr. No	Name of Member	Qualification	Role in EC (Scientific/ Non-scientific)	Gender (M/F)	Affiliated with Institution (Yes/No)
1.	Dr. V. M. Divekar	MD(Anesthesia)	Chairperson (Scientific)	Female	No
2.	Dr. Renuka Munshi	MD(Pharmacology); DNB (Clinical Pharmacology)	Secretary (Scientific)	Female	Yes
3.	Dr. Anita Shenoy	MD (Community Medicine)	Scientific	Female	Yes
4.	Dr. Subodh Sirur	MD(Dermatology), LLM	Scientific	Male	No
5.	Mrs. Manisha Naikdalal	M. Com	Lay Person	Female	No
6.	Mrs. Sanjivani Shetye	MA (Social Work)	MSW	Female	No
7.	Ms. Aditi Nabar	LLB	Legal Member	Female	No

It is hereby confirmed that neither you nor any of the study team members have participated in the voting/decision making procedure of the Committee.

Secretariat: TN Medical College & BYL Nair Ch. Hospital, , 5th floor, G bldg, c/o Department of Clinical Pharmacology, Dr AL Nair Road, Mumbai Central, Mumbai 400 008. Tel: 91-22-2302 7205;
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The ECARP has reviewed and approved the following documents submitted for the above mentioned research study.

1. Study Protocol Version 1.1 dated 18 May 2020
2. Request for Waiver of Informed Consent
3. Annexure 1 – Case Record Form for data collection for the prospective arm (Part B) Version 1.1 dated 18 May 2020
4. Annexure II (Systematic review pre-print)
5. Excel sheets for retrospective data collection (Part A) of women with COVID- 19 and newborn of women with COVID-19
6. Draft MOU between ICMR-National Institute for Research In Reproductive Health (ICMR-NIRRH) & Topiwala National Medical College (TNMC) & B. Y. L. Nair Charitable Hospital
7. CVs of Dr Niraj Mahajan & Dr Rahul Gajbhiye
8. GCP Certificates of the Study Team members from both study sites

The ECARP has unanimously approved your research project entitled '**National Registry of Pregnant women with COVID-19 in India - PregCovid study**'. It is understood that the study will be conducted in collaboration with **Dr Rahul Gajbhiye**, Scientist D, ICMR-NIIRH. The Study Co-Investigators include **Dr Ganesh Shinde**, Professor & Head, **Dr. Arundhati Tilve**, Assistant Professor, **Dr Rahi Pednekar**, Assistant Professor, **Dr Chaitanya Gaikwad**, Assistant Professor & **Dr Deepika Tirkey**, Speciality Medical Officer from the Department of Obstetrics & Gynecology; **Dr. Sushma Mallik**, Professor & Head, **Dr Poonam Wade**, Associate Professor & **Dr Santosh Kondekar**, Associate Professor from the Department of Paediatrics. It is understood that the study will be conducted at the Department of Obstetrics & Gynecology, TN Medical College & BYL Nair Hospital as per the submitted protocol. It is understood that the project will be conducted in all COVID-19 positive pregnant women admitted at BYL Nair Hospital as per the submitted protocol. The study is planned to be conducted in 2 parts: Part A being the retrospective arm wherein the medical case records of pregnant women with COVID-19 admitted at BYL Nair Charitable Hospital from 1st January 2020 to 31st May 2020 will be analyzed retrospectively while Part B is the prospective arm wherein the medical case records of all pregnant and/ post-partum women with COVID-19 at BYL Nair Charitable Hospital, Mumbai will be reviewed from 1st June 2020 for a period of 24 months i.e. 31st May 2022.

No deviation from, or changes of the Protocol and other study documents, should be initiated without prior written approval by the ECARP of an appropriate amendment. The ECARP expects that the investigator should promptly report to the ECARP any deviations from or changes of, the protocol to eliminate immediate hazards to the trial participants and about any new information that may affect adversely the safety of the participants or the conduct of the trial. The ECARP functions in accordance with ICH-GCP (1996), Indian GCP (2001) and ICMR National Ethical Guidelines for Biomedical and Health Research involving Human participants (2017).

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You are requested to submit the EC approval of the other sites to the ECARP as they are obtained and a copy of the Electronic Patient Record (EPR) software that will be used for data entry of the study related information.

Bi-annual Progress reports of the study should be submitted to the ECARP for review. A copy of the final Completion report should be submitted to the ECARP at the end of the study.

Warm regards,

Dr. Renuka Munshi
Hon. Member Secretary

Date of approval of the study: 27th May 2020