

February 01, 2022

To,
Dr. Atul Kulkarni,
Principal Investigator,
Department of Anaesthesia
Tata Memorial Hospital

Ref: Project No. 3922 :- "aDverse EvenTs duRing artificial airway Management in Indian ICUs (DETRIMENT): A prospective multicentre cohort study"

Dear Dr. Kulkarni,

The following documents for the above referenced project were reviewed during the Institutional Ethics Committee-I (IEC-I) meeting held on 25/01/2022 at 9.00 am via videoconferencing.

1. Project submission form
2. Protocol version 1.0 dated 01/01/2022
3. Case record form version 1.0 dated 01/01/2022
4. Lay summary version 1.0 dated 01/01/2022
5. Application form for requesting waiver of consent
6. Data sharing Agreement 1.0 dated 01/01/2022
7. CVs, GCP & MRCs of Principal investigator and Co-investigators

The following members of the Institutional Ethics Committee-I were present:

Sr. No.	Name	Position	Affiliation	Affiliation Status	Gender	Expertise
1.	Dr. Nithya Gogtay	Chairperson	Professor & Head, Department of Clinical Pharmacology, KEM Hospital	Non Affiliated	Female	Basic Medical Scientist (Clinical Pharmacologist)
2.	Dr. Sangeeta Mudaliar	Co-Chairperson	Full Time Consultant & Head of the Department, Paediatric Hemato-Oncology B J Wadia Hospital	Non Affiliated	Female	Medical Oncologist (Pediatician)
3.	Dr. Gouri Pantvaideya	Member Secretary	Professor, Department of Surgical Oncology, Tata Memorial Hospital	Affiliated	Female	Surgeon
4.	Mr. KV Ganpathy	Member	CEO, Jeet Association for Support to Cancer Patients (JASCAP)	Non Affiliated	Male	Lay Person
5.	Dr. Mrunal Marathe	Member	Freelance Counselor and Trainer associated with NGO-St. Jude's-Childcare Centre and Adoption Group, Asha Sadan Orphanage	Non Affiliated	Female	Social scientist

Sr. No.	Name	Position	Affiliation	Affiliation Status	Gender	Expertise
6.	Mr. N D Jaywant	Member	Advocate, High court, Mumbai	Non Affiliated	Male	Legal expert
7.	Dr. Sachin Satpute	Member	Asst. Professor, Dept. of Pharmacology, Topiwala National Medical College & BYL Nair Ch.Hospital	Non Affiliated	Male	Basic Medical Scientist (Clinical Pharmacologist)
8.	Dr. Bharatsinha Bhosale	Member	Senior consultant Oncologist, Bombay Hospital medical and Research Institute Visiting Consultant Oncologist Jaslok Hospital Medical & Research Institute, SL Raheja Fortis group of Hospital	Non Affiliated	Male	Medical Oncologist
9.	Dr. Maya Prasad	Member & Secretary, Data Safety Monitoring Unit (DSMU)	Professor, Department of Medical (Paediatric) Oncology, Tata Memorial Hospital	Affiliated	Female	Medical Oncologist (Pediatician)
10.	Dr. Santosh Menon	Member	Professor, Department of Pathology, Tata Memorial Hospital	Affiliated	Male	Basic Medical Scientist (Pathologist)
11.	Dr. Prakash Nayak	Member	Assistant Professor, Department of Surgical Oncology, Tata Memorial Hospital	Affiliated	Male	Surgeon
12.	Dr. Jeson Doctor	Member	Professor, Department of Anaesthesia, Critical Care and Pain, Tata Memorial Hospital	Affiliated	Male	Anesthesiologist
13.	Dr. Sabita Jiwnani	Member	Associate Professor, Department of Surgical Oncology, Tata Memorial Hospital	Affiliated	Female	Surgeon
14.	Dr. Tabassum Wadasadawala	Member	Professor, Department of Radiation Oncology, Tata Memorial Hospital	Affiliated	Female	Radiation Oncologist

IEC comments were as follows:

- 1) To include height, weight, distance of fixation of ETT, SOFA score and cuff pressure in the CRF according to the protocol
- 2) Will the patient records define what is 'blocked' ET tube or 'Malposition'?
- 3) To clarify if data variables (points 18 to 21) will be available on EMR and the methodology to assess these variables should be put in the protocol.

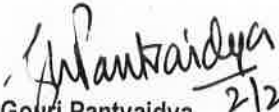
- 4) To provide details of participating centres and MOUs with them
- 5) IEC form- sign of Dr. Kushal pending
- 6) MoU- Clause : Term and Termination of Data Sharing Agreement provides that the Data Sharing Agreement or any portion thereof may be terminated. This termination of a portion of the Agreement is improper. If either party has a problem with any part of the agreement, the same can be modified by executing a fresh agreement.
- 7) Incase of any adverse events, PI to fill in the materiovigilance form available on the CDSCO website
- 8) The waiver of consent cannot be granted as it is a prospective data collection in a vulnerable group of patients who are critically ill. PI to obtain consent from the patient's relative and deferred consent to be taken.

Status: Revision with major modifications for resubmission. Kindly comply with the above suggestions of the IEC and submit one copy of revised proposal or documents on or before 25/07/2022 for review. If you fail to submit within this period, this project will be closed by IEC and you will have to submit a new project

This decision was taken unanimously.

Neither PI nor any of proposed study team members participated during the decision making of the IEC. IEC members with any conflict of interest opted out from all deliberations on the proposal and did not participate in decision making.

Thanking you,


Dr. Gouri Pantvaidya, 21/2/22
Member Secretary,
Institutional Ethics Committee-I