TATA MEMORIAL CENTRE
टाटा स्मारक केन्द्र
TATA MEMORIAL HOSPITAL
टाटा स्मारक अस्पताल
प.ऊ.वि. भारत सरकार का एक सहायता अनुदान प्राप्त संस्थान
A GRANT-IN-AID INSTITUTION UNDER DEPARTMENT OF ATOMIC ENERGY, GOVT. OF INDIA
टाटा स्मारक केंद्र
Tata Memorial Centre

INSTITUTIONAL ETHICS COMMITTEE
DCGI Reg. No. :
IEC I :- ECR/170/Inst/MH/2013/RR-19
IEC II :- ECR/414/Inst/MH/2013/RR-19

OIEC/3922/2022/00003

April 04, 2022

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

Ref: Final Approval - 3922

Dear Dr. Kulkarni,

Institutional Ethics Committee reviewed and discussed your application dated **11/01/2022** to conduct the research study entitled **"aDverse EvenTs duRing artIficial airway ManagemENT in Indian ICUs (DETRIMENT): A prospective multicentre cohort study"** during the Institutional Ethics Committee-I meeting held on **22/03/2022 at 09:00 am in the IRB Meeting Room, Main bldg., 3rd Floor, Tata Memorial Hospital.**

The proposal was initially tabled in the IEC-I meeting held on **25/01/2022** and had attained "Revisions with major modifications for resubmission" status and a letter dated **01/02/2022** was issued addressing key concerns in the proposal. The project was resubmitted to IEC on **15/03/2022** and was re-reviewed in the IEC-I meeting held on **22/03/2022.**

At the IEC-I meeting held on **22/03/2022**, the Committee, after due consideration had raised certain queries and IEC query letter dated **29/03/2022** was issued.

We received query response on **31/03/2022** and the supporting documents which were reviewed and approved on **04/04/2022.**

The following documents were reviewed and approved

1. Project submission form
2. Response dated 24.02.2022
3. IEC form for re-review of research proposals
4. Study protocol version 2.0 dated 03.02.2022
5. Case record form version 2.0 dated 03.02.2022
6. Lay summary version 1.0 dated 01/01/2022
7. Short consent form for Legally Acceptable Representative & deferred consent version1.0 dated 03.02.2022 in English, Hindi and Marathi
8. Data sharing agreement
9. CVs, GCP & MRCs of Principal investigator and Co-investigators

The following members of the Institutional Ethics Committee-I were present during the IEC meeting held on **22/03/2022 at 09:00 am in the IRB Meeting Room, Main bldg., 3rd Floor, Tata Memorial Hospital.**

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 (Pediatrician)
3.	Dr. Gouri Pantvaidya	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
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 (Pediatrician)
10.	Dr. Santosh Menon	Member	Professor, Department of Pathology, Tata Memorial Hospital	Affiliated	Male	Basic Medical Scientist (Pathologist)

Sr. No.	Name	Position	Affiliation	Affiliation Status	Gender	Expertise
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

The study is approved in its present form for a period of 1 Years till 03/04/2023. The Principal Investigator should submit continuing review application/annual status report on or before 03/02/2023. You may request for extension of validity in the submission of continuing review application/annual status report. In order to ensure that there is no lapse in the IEC approval period, it is mandatory to submit study status report prior to lapse of study validity.

- **PI should intimate IEC on any extramural funding obtained as part of educational/unconditional support and/or other sources. Agreement/MoU as per IEC approved template with the funding bodies should be submitted to the IEC, prior to starting accrual on the study.**
- **It is mandatory that the source documentation should be done in the electronic medical record and case file.**
- **If the study requires institutional insurance coverage, please confirm this with TRAC administrator after IEC approval and before commencing the study.**
- **Patients shall be recruited from ICU at Tata Memorial Hospital.**

The study should be initiated only after –

- **Registration of the study with Clinical Trials Registry India (CTRI).**
- **Submission of Finalized and signed Data sharing agreement to IEC.**

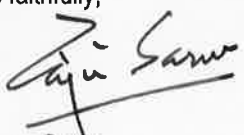
Following points must be noted:

1. **IEC has approved recruitment of 100 participants on this study.**
2. **IEC has approved the conduct of the study at TMH.**
3. **As per TRAC circular dated 19 May 2021, please ensure that TRAC is informed about all sources of funding prior to starting the study.**
4. Principal Investigator and study team should be GCP trained
5. PI and other investigators should notify initiation of the study. Principal Investigator should intimate the IEC after accrual of first 10 participants in the study or after 6 months of initiation of study whichever is earlier.

6. PI and other investigators should co-operate fully with data and safety monitoring unit (DSMU), who will monitor the study from time to time.
7. The decision was arrived at through consensus/unanimous or majority opinion amongst the voting members of IEC. Member(s) of the committee who is/are listed as investigator(s) on a research proposal opted out from all deliberations on the proposal and did not participate in decision making. Neither PI nor any of proposed study team members participated during the decision making of the IEC.
8. At the time of PI's retirement/intention to leave the institute, study responsibility should be transferred to colleague after obtaining clearance from HOD and/or convener of the PI's DMG and IEC. Status report, including accounts details should be submitted to HOD and extramural sponsors.
9. The IEC functions in accordance with its SOP and is compliant with the New Drugs & Clinical Trial Rules, 2019, ICMR guidelines and Indian/ICH GCP
10. In the events of any protocol amendments, IEC must be informed and the amendments should be highlighted in clear terms as follows:
    a) The exact alteration/amendment should be specified and indicated where the amendment occurred in the original project. (Page no. Clause no. etc.)
    b) Alteration in the budgetary status should be clearly indicated and the revised budget form should be submitted
    c) If the amendments require a change in the consent form, the copy of revised Consent Form should be submitted to Institutional Ethics Committee for approval.
    d) If the amendment demands a re-look at the toxicity or side effects to patients, the same should be documented.
    e) If there are any amendments in the study design, these must be incorporated in the protocol, and other study documents. These revised documents should be submitted for approval of the IEC, only then can they be implemented.
    f) Approval for amendment changes must be obtained prior to implementation of changes. Without including all the above points, the amendment is unlikely to be approved by the IEC.
11. Any Serious Adverse Events (SAEs) occurring on the study should be reported to IEC
12. Any deviation/violation/waiver in the protocol must be informed to the IEC.
13. Principal Investigator should conduct the study in accordance with the IEC approved protocol
14. The PI should submit study completion report to the IEC at the time of study completion or Premature Termination / Suspension / Discontinuation Report as is applicable
15. Principal Investigator should comply with regulations and guidelines as applicable

Thanking You,

Yours faithfully,



Dr. Rajiv Sarin
Member Secretary,
Institutional Ethics Committee-I