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 OF THE DEPARTMENT OF ATOMIC ENERGY, GOVT. OF INDIA

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

IEC/0920/3559/001

September 21, 2020

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

Ref: Final Approval - 3559

Dear Dr. Kulkarni,

Institutional Ethics Committee reviewed and discussed your application dated **23/07/2020** to conduct the research study entitled **"NATIONAL (iNdian AnalgosedaTION And deLirium) : Multi-center Prospective Observational Study of Current Analgo-Sedation Practices and the incidence of delirium in Indian ICUs: INSTINCT II study (INhaled SedaTion INCriTically ill patients -INSTINCT study Group)"** during the Institutional Ethics Committee-II meeting held **via video-conferencing (Zoom meeting) on 14/08/2020 at 1.30 p.m.**

At the IEC-II meeting held on **14/08/2020**, the Committee, after due consideration had raised certain queries and IEC query letter dated **17/08/2020** was issued.

We received query response on **25/08/2020** and the supporting documents which were reviewed and approved on **21/09/2020.**

The following documents were reviewed and approved

1. Project submission form
2. Study protocol version 2.0 dated 24.08.2020
3. Lay summary version 1.0 dated 22.06.2020
4. Case record form version 1.0 dated 22.06.2020
5. Participant information sheet and short consent for LAR version 1.0 dated 22.06.2020 in English, Hindi, Marathi
6. Participant information sheet and deferred consent version 1.0 dated 22.06.2020 in English, Hindi, Marathi
7. Draft Memorandum of Understanding between Indian Society of Critical Care Medicine (ISCCM) & Tata Memorial Hospital version 2.0 dated 24.08.2020
8. Response letter dated 25.08.2020
9. IEC form for re-review of research proposals dated 24.08.2020
10. CVs, GCP & MRC certificates of Principal investigator and Co-investigators

The following members of the Institutional Ethics Committee-II were present during the IEC meeting held **via video-conferencing (Zoom meeting) on 14/08/2020 at 1.30p.m.**

Sr. No.	Name	Position	Affiliation	Gender	Expertise
1.	Dr.Shyam Kishore Shrivastava	Chairperson	Director, Radiation Oncology, Apollo Hospital	Male	Radiation Oncologist
2.	Dr.Priya Ranganathan	Member Secretary & Clinician	Professor, Dept. of Anaesthesia, Tata Memorial Hospital	Female	Anesthetist
3.	Dr.Padmaja Marathe	Basic Medical Scientist	Prof. (Additional), Dept of Pharmacology and Therapeutics, Seth GS Medical College and KEM Hospital, Mumbai	Female	Clinical Pharmacologist
4.	Mrs.Manisha Naikdalal	Lay Person	Member of Ethics Committees at Hinduja Hospital (IEC-1),IITB, Global Hospital, Nair Hospital, ISBEC (InterSystems Biomedica Ethics Committee), Alternate Member (Layperson) at KEM Hospital and Lilavati Hospital	Female	Lay Person
5.	Dr.Bindulakshmi P	Social scientist	Associate Professor, Advanced Centre for Women's Studies, School of Development Studies, Tata Institute of Social Sciences	Female	Social scientist
6.	Mr. Agnel Carneiro	Legal Expert	Advocate Associate, Mulla & Mulla & Craigie Blunt & Caroe, Mulla House,51 Mahatma Gandhi Road, Fort, Mumbai 400 001	Male	Legal expert
7.	Dr. Gaurav Narula	Clinician	Professor, Dept. of Medical Oncology (pediatric), Tata Memorial Hospital	Male	Medical Oncologist
8.	Dr. Nehal Khanna	Joint Secretary, Data Safety Monitoring Unit (DSMU) & Clinician	Associate Professor, Dept. of Radiation Oncology, Tata Memorial Hospital	Female	Radiation Oncologist
9.	Dr. Shivakumar Thiagarajan	Clinician	Associate Professor, Head And Neck Oncology, Tata Memorial Hospital	Male	Surgeon
10.	Dr.Nita Nair	Clinician	Professor, Surgical Oncology (Breast Service), Tata Memorial	Female	Surgeon

Sr. No.	Name	Position	Affiliation	Gender	Expertise
			Hospital		
11.	Dr.Nilesh Lokeshwar	Clinician	Consultant, Asian Cancer Institute, Sion (E), Mumbai	Male	Medical Oncologist
12.	Dr.Munita Bal	Clinician	Professor, Dept. of Pathology, Tata Memorial Hospital	Female	Basic Medical Scientist (Pathologist)
13.	Dr.Nilendu Purandare	Clinician	Professor, Dept. of Nuclear Medicine, Tata Memorial Hospital	Male	Radiologist

The study is approved in its present form for a period of 1 year till 20/09/2021. The Principal Investigator should submit continuing review application/annual status report on or before 20/07/2021. 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.

- **The source documentation should be done in the electronic medical record and case file.**
- **Project related expenditure should not be made from trust accounts/Rajiv Gandhi etc**

The study should be initiated only after –

- **Registration of the study with Clinical Trials Registry India (CTRI).**
- **Submission of Finalized Memorandum of Understanding to IEC**

Following points must be noted:

1. **IEC has approved recruitment of 50 participants on this study.**
2. **IEC has approved the conduct of the study at TMH**
3. Principal Investigator and study team should be GCP trained
4. 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.
5. PI and other investigators should co-operate fully with data and safety monitoring unit (DSMU), who will monitor the study from time to time.
6. 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.
7. 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.
8. 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

9. 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.
10. Any Serious Adverse Events (SAEs) occurring on the study should be reported to IEC
11. Any deviation/violation/waiver in the protocol must be informed to the IEC.
12. Principal Investigator should conduct the study in accordance with the IEC approved protocol
13. The PI should submit a report to the IEC at the time of study completion / premature termination / suspension / discontinuation, as is applicable
14. Principal Investigator should comply with regulations and guidelines as applicable

Thanking You,

Yours Sincerely,

Priya Ranganathan 21/Sep/2020

Dr. Priya Ranganathan,
Member Secretary,
Institutional Ethics Committee-II