



TATA MEMORIAL CENTRE
टाटा स्मारक केन्द्र
TATA MEMORIAL HOSPITAL
टाटा स्मारक अस्पताल

INSTITUTIONAL ETHICS COMMITTEE

IEC/0719/3315/001

July 11, 2019

To,
Dr. Maya Prasad,
Principal Investigator,
Department of Medical Oncology,
Tata Memorial Centre.

Ref: Final Approval - 3315

Dear Dr. Prasad,

Institutional Ethics Committee reviewed and discussed your application dated 14/05/2019 to conduct the research study entitled "An observational, comparative study to evaluate the proteomic and metabolic profile of blood serum in cancer patients belonging to two different nutritional groups " during the Institutional Ethics Committee-I meeting held on 29/05/2019 at 8:30 a.m. in the IRB Meeting Room, Main bldg., 3rd Floor, Tata Memorial Hospital.

At the IEC-I meeting held on 29/05/2019, the Committee, after due consideration had raised certain queries and IEC query letter dated 04/06/2019 was issued.

We received query response on 18/06/2019 and the supporting documents which were reviewed and approved on 11/07/2019.

The following documents were reviewed and approved

1. Project Submission form
2. IEC form for re-review of research proposals
3. Study protocol version 1.1 dated 14/06/2019
4. Case record form version 1.0 dated 30/04/2019
5. Parent information sheet and informed consent form version 1.0 dated 30/04/2019 in English, Hindi, Marathi
6. Child information sheet and assent form version 1.1 dated 14/06/2019 in English, Hindi, Marathi
7. Lay summary version 1.0 dated 30/04/2019
8. 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 29/05/2019 at 8:30 a.m. in the IRB Meeting Room, Main bldg., 3rd Floor, Tata Memorial Hospital.

Sr. No.	Name	Position	Affiliation	Gender	Expertise
1.	Dr. S.K. Shrivastava	Chairperson	Director, Radiation Oncology, Apollo Hospital	Male	Radiation Oncologist
2.	Dr. Nithya Gogtay	Co-Chairperson	Professor, Dept of Clinical Pharmacology, KEM Hospital	Female	Basic Medical Scientist (Clinical Pharmacologist)

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आय ई सी ऑफिस
डॉ. ई. बोरजेस मार्ग, परेल,
मुंबई - ४०० ०१२, भारत
दूरभाष : ०२२ - २४१७ ७२६२
फैक्स : ०२२ - २४१५ ४००५

Cancer is curable, if detected early

जल्द इलाज होने पर कैंसर ठीक हो सकता है।

Sr. No.	Name	Position	Affiliation	Gender	Expertise
3.	Dr. Umesh Mahantshetty	Member Secretary	Professor, Dept. of Radiation Oncology, Tata Memorial Hospital	Male	Radiation Oncologist
4.	Dr. Gouri Pantvaidya	Member & Secretary, Data Safety Monitoring Unit (DSMU)	Professor, Dept. of Surgical Oncology, Tata Memorial Hospital	Female	Surgeon
5.	Mr. KV Ganpathy	Member	CEO, Jeet Association for Support to Cancer Patients (JASCAP)	Male	Lay Person
6.	Dr. Sheila Myatra	Member	Professor, Dept. of Anesthesiology, Critical Care and Pain, Tata Memorial Hospital	Female	Anesthetist
7.	Dr. Mrunal Marathe	Member	Freelance Counselor and Trainer associated with NGO- St.Jude's- Childcare Centre and Adoption Group, Asha Sadan Orphanage	Female	Social scientist
8.	Ms. Tanu Mehta	Member	Legal Counsel and Mediator, High Court, Mumbai	Female	Legal expert
9.	Dr. Sudhir Nair	Member	Associate Professor, Dept. of Surgical Oncology, Tata Memorial Centre	Male	Surgeon
10.	Dr. Palak Popat	Member	Assistant Professor, Dept. of Radiodiagnosis, Tata Memorial Hospital	Female	Radiologist
11.	Dr. Sneha Shah	Member	Professor, Nuclear Medicine, Bio-imaging Unit, Tata Memorial Hospital	Female	Nuclear Medicine Physician
12.	Dr. Vikas Ostwal	Alternate Member	Associate Professor, Dept. of Medical Oncology, Tata Memorial Hospital	Male	Medical Oncologist
13.	Dr. Gaurav Narula	Alternate Member	Professor, Dept. of Medical Oncology, (Pediatric), Tata Memorial Hospital,	Male	Pediatrician

The study is approved in its present form for a period of 1 year till 10/07/2020. The Principal Investigator should submit continuing review application/annual status report on or before 10/05/2020. 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 study should be initiated only after –

- **Registration of the study with Clinical Trials Registry India (CTRI).**

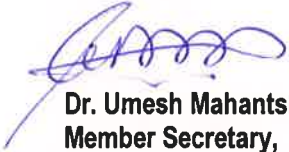
Following points must be noted:

1. **IEC has approved recruitment of 50 participants on this study.**
2. **IEC has approved the conduct of the study at TMH+ACTREC**
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 study completion report to the IEC at the time of study completion or Premature Termination / Suspension / Discontinuation Report as is applicable
14. Principal Investigator should comply with regulations and guidelines as applicable

Thanking You,

Yours Sincerely,



**Dr. Umesh Mahantshetty,
Member Secretary,
Institutional Ethics Committee-I**



टाटा स्मारक केन्द्र
TATA MEMORIAL CENTRE

कैंसर उपचार, अनुसंधान एवं शिक्षा का प्रगत केन्द्र
ADVANCED CENTRE FOR TREATMENT RESEARCH
& EDUCATION IN CANCER

- CANCER RESEARCH INSTITUTE
- CLINICAL RESEARCH CENTRE
- CENTRE FOR CANCER EPIDEMIOLOGY

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

68622

23.11.2022

To whom it may concern

This is to certify that Dr. Soumen Manna is a collaborator on the study titled 'An observational, comparative study to evaluate the proteomic and metabolic profile of blood serum in cancer patients belonging to two different nutritional groups'. As a collaborator he is involved in metabolomics analysis of serum samples collected in this study.

Dr. Vikram Gota

Professor, Clinical Pharmacology

ACTREC, Tata Memorial Centre

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Cancer is curable, if detected early.