



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

Institutional Ethics Committee
w.e.f. 15th October, 2013

INSTITUTIONAL REVIEW BOARD

IEC/0518/3023/001

May 08, 2018

To,
Dr. Girish Chinnaswamy,
Principal Investigator,
Department of Medical Oncology,
Tata Memorial Centre.

Ref: Final Approval - 3023

Dear Dr. Chinnaswamy,

Institutional Ethics Committee reviewed and discussed your application dated **20/02/2018** to conduct the research study entitled "**Precision medicine and Malnutrition- A Model based approach to dose chemotherapy in pediatric patients with malnutrition**" during the Institutional Ethics Committee-I meeting held on **21/03/2018** at **8:30 a.m. in the IRB Meeting Room, Main bldg., 3rd Floor, Tata Memorial Hospital.**

At the IEC-I meeting held on **21/03/2018**, the Committee, after due consideration had raised certain queries and IEC query letter dated **26/03/2018** was issued.

We received query response on **18/04/2018** and the supporting documents which were reviewed and approved on **08/05/2018**.

The following documents were reviewed and approved

1. Project Submission Form
2. Study protocol version 2 dated April 2018
3. Case record form version 1 dated 21/11/2017
4. Parent Information Sheet and Informed Consent Form Version 1.0 dated: 20/11/2017 in English, Hindi and Marathi
5. Child Information Sheet and Assent Form Version 1.0 dated: 20/11/2017 in English, Hindi and Marathi
6. Draft Memorandum of Understanding (MoU) with Northern Institute of Cancer Research, Newcastle (Dr Gareth Veal)
7. Draft Memorandum of Understanding (MoU) with Indian Institute of Science (Dr. Utpal Tatu)
8. Letter of support dated 23/10/2017 from Dr Gareth Veal
9. Letter of support dated 25/10/2017 from Dr Utpal Tatu
10. CVs, GCP and MRC of Principal Investigator and Co-investigators

IRB Office
Dr. E. Borges Marg, Parel,
Mumbai - 400 012, India
Phone : 022-2417 7262
Fax : 022-22 2415 4005

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आय आर बी 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।

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The following members of the Institutional Ethics Committee-I were present during the IEC meeting held on 21/03/2018 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. Tapan Saikia | Chairperson | Head, Dept of Medical Oncology & Research Director, Prince Aly Khan Hospital, Mazagaon, Mumbai | Male | Medical Oncologist |
| 2. | Dr. Nithya Gogtay | Co-chairperson | Professor, Dept of Clinical Pharmacology, KEM Hospital | Female | Basic Medical Scientist (Clinical Pharmacologist) |
| 3. | Dr. George Karimundackal | Member Secretary | Professor, Dept. of Surgical Oncology, Tata Memorial Hospital | Male | Surgeon |
| 4. | Dr. Prachi Patil | Member & DSMSC Secretary | Associate Professor, Dept. of Digestive Diseases & Clinical Nutrition, Tata Memorial Hospital | Female | Gastroenterologist |
| 5. | Ms. Manisha Naikdalal | Member | Member of Ethics Committees at Hinduja Hospital, Global Hospital, Nair Hospital, IIT Bombay | Female | Lay Person |
| 6. | Prof. Bindhulakshmi P | Member | Associate Professor, Advanced Centre for Women's Studies, School of Development Studies, Tata Institute of Social Sciences | Female | Social scientist |
| 7. | Dr. Suganthi Iyer | Member | Dy. Director (Legal & Medical) Hinduja Hospital | Female | Legal expert |
| 8. | Dr. Sanjay Gupta | Member | Scientific Officer, CRI- Advanced Centre for Treatment, Research and Education in Cancer (ACTREC) | Male | Basic Scientist |
| 9. | Dr. Amit Joshi | Member | Professor, Dept. of Medical Oncology, Tata Memorial Hospital | Male | Medical Oncologist |
| 10. | Dr. Tanuja Shet | Member | Professor, Dept of Pathology, Tata Memorial Hospital | Female | Basic Medical Scientist (Pathologist) |
| 11. | Mr. Sanjay Talole | Member | Scientific Officer, Dept of Medical records, Tata Memorial Hospital | Male | Statistician |
| 12. | Dr. Umesh Mahantshetty | Alternate Member | Professor, Dept. of Radiation Oncology, Tata Memorial Hospital | Male | Radiation Oncologist |
| 13. | Dr. (Surg. Cdr) Gaurav Narula | Alternate Member | Professor Pediatric Oncology, Convener Pediatric Hematolymphoid Group, Tata Memorial Center | Male | Medical Oncologist (Pediatrician) |

Independent expert (Pediatrician) provided the expert opinion and did not participate in the decision making.

The study is approved in its present form for a period of 60 months till 07/05/2023. The Principal Investigator should submit continuing review application/annual status report on or 07/03/2019. 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).
- Submission of Finalized Memorandum of Understanding to IEC
- Submission of Health Ministry's Screening Committee (HMSC) approval to IEC

Following points must be noted:

1. IEC has approved recruitment of 500 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 Sub-committee (DSMSC), 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 Schedule Y (Drugs & Cosmetic Act 1940), 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.

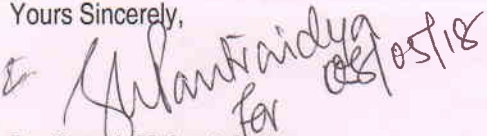
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- e) If there are any amendments in the study design, these must be incorporated in the protocol, and other study documents. These revised documents should be submitted for approval of the IEC, only then can they be implemented.
- f) Approval for amendment 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