OIEC/4148/2023/00002

March 30, 2023

To,
Dr. Gaurav Chatterjee,
Principal Investigator,
Department of Hemato-pathology,
Tata Memorial Centre.

**Ref: Final Approval - 4148**

Dear Dr. Chatterjee,

Institutional Ethics Committee reviewed and discussed your application dated **01/03/2023** to conduct the research study entitled **"Deciphering the molecular heterogeneity in Acute Leukemia of Ambiguous Lineage at a cellular level"** during the Institutional Ethics Committee-I hybrid meeting held on **14/03/2023 at 9.00 am in Institutional Review Board Meeting Room, Main Bldg, 3rd Floor, Tata Memorial Hospital.**

At the IEC-I meeting held on **14/03/2023**, the Committee, after due consideration had raised certain queries and IEC query letter dated **14/03/2023** was issued.

We received query response on **23/03/2023** & **29/03/2023** and the supporting documents which were reviewed and approved on **30/03/2023.**

The following documents were reviewed and approved

1. Project submission form
2. IEC form for re-review of research proposals
3. Response letter dated 23/03/2023
4. Response letter dated 28/03/2023
5. Protocol version 1.1 dated 20/02/2023
6. Case record form version 1.2 dated 20/03/2023
7. Parent information sheet and informed consent form version 1.1 dated 20/02/2023 in English, Hindi, Marathi
8. Child information sheet and Assent form version 1.2 dated 20/03/2023 in English, Hindi, Marathi
9. Patient Information sheet and informed consent form version 1.2 dated 20/03/2023 in Hindi
10. Lay summary version 1.2 dated 20/03/2023
11. Summary of changes list dated 23/03/2023
12. CVs, GCP & MRCs of Principal investigator and Co-investigators



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आय.ई.सी. ऑफीस
डॉ.ई. बोर्जेस मार्ग, परेल,
मुंबई - ४०० ०१२. भारत
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The following members of the Institutional Ethics Committee-I were present during the IEC hybrid meeting held on **14/03/2023 at 9.00 am in Institutional Review Board 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. Rajiv Sarin | Member Secretary | Professor, Radiation Oncology & PI & OIC, Cancer Genetics Unit, Tata Memorial Hospital | Affiliated | Male | Clinician (Radiation Oncologist) |
| 4. | Dr. K V Ganpathy | Member | CEO,Jeet Association for Support to Cancer Patients (JASCAP) | Non Affiliated | Male | Lay Person |
| 5. | Mrs. Nivedita Sinha | Member | Freelance patient volunteer | Non Affiliated | Female | Lay Person |
| 6. | 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 |
| 7. | Dr. Astrid Lobo-Gajiwala | Member | Director & CEO Novo Tissue Bank and Research Centre Pvt. Ltd.CSM Road, Vakola, Santa Cruz | Non Affiliated | Female | Social scientist |
| 8. | Mr. N D Jaywant | Member | Advocate, High court, Mumbai | Non Affiliated | Male | Legal expert |
| 9. | Mr. Rajeev Talasikar | Member | Advocate & Legal Consultant Rajeev & Associates, Mumbai | Non Affiliated | Male | Legal expert |
| 10. | 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) |
| 11. | Dr. Uma Dangi | Member | Senior Consultant, Dept of Medical Oncology, Fortis Hospital, Mulund | Non Affiliated | Female | Clinician (Medical Oncologist) |

| Sr. No. | Name | Position | Affiliation | Affiliation Status | Gender | Expertise |
|---|---|---|---|---|---|---|
| 12. | Dr. Swapnil Parab | Member & Secretary, Data Safety Monitoring Unit (DSMU) | Professor, Dept of Anaesthesiology, Tata Memorial Hospital | Affiliated | Male | Clinician (Anesthesiologist) |
| 13. | Dr. Prakash Nayak | Member | Associate Professor, Department of Surgical Oncology, Tata Memorial Hospital | Affiliated | Male | Clinician (Surgeon) |

**The study is approved in its present form for a period of 3 Years till 29/03/2026. The Principal Investigator should submit continuing review application/annual status report on or before 30/01/2024. 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.**
- **Patients shall be recruited from Tata Memorial Hospital and ACTREC on OPD basis.**

**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. **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**