

Tata Medical Center

14 Major Arterial Road (EW)
Newtown, Rajarhat, Kolkata - 700 160
Tel.: + 91 33 66057000, Email : info@tmckolkata.com
www.tmckolkata.com



UNDERTAKING BY THE INVESTIGATOR

To

The Drugs Controller General of India
Directorate General of Health Services
FDA Bhawan, CHEB Campus, Kotla Road,
New Delhi – 110002. India.

Date: 08.07.2026

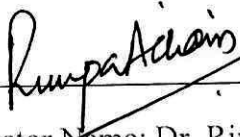
1.	Full name, address and title of the principal Investigator (or Investigator(s) when there is no Principal Investigator)
2.	Name and address of the medical college, hospital or other facility where the clinical trial will be conducted: Education, training & experience that qualify the Investigator for the clinical trial (Attach details including Medical Council registration number, and / or any other statement(s) of qualification(s)) Tata Medical Center, 14 MAR EW, Newtown, Rajarhat, Kolkata, West Bengal, 700160 Qualification: MBBS, MD (Radiation Oncology) <i>CV & Practice Registration Certificate of the Investigator is enclosed</i>
3.	Name and address of all clinical laboratory facilities to be used in the study
a.	Local Laboratory: Department of Laboratory Sciences Tata Medical Center Kolkata
b.	Central Laboratory: Metropolis Healthcare Pvt. Ltd. Mumbai, Maharastra
4.	Name and address of the Ethics Committee that is responsible for approval and continuing review of the study Name: Institutional review Board. Address: 14, MAR (EW) Newtown Rajarhat Kolkata-700160 EC Registration Number: IECR/269/Inst/WB/2013/rr-24
5.	Name of the other members of the research team (Co-or Sub-Investigators) who will be assisting the Investigator in the conduct of the investigation(s) <i>Sub Investigator: Dr. Paromita Roy, Dr. Reghu K.S, Dr. Susmita Sadhukhan, Dr. Aiswarya Raveendran</i> <i>Qualification: MBBS, MD (Pathology), MBBS, MD (Pediatrics), MBBS, DM, MD (Medical Oncology), MBBS, MD (Radiation Oncology).</i>

6.	Protocol Title and Study number (if any) of the clinical trial to be conducted by the Investigator
	<i>Protocol Number:</i> SER-VOR-001
	<i>Protocol Version & Date:</i> Version 1.0 dated 24 Apr 2026
	<i>Protocol Title:</i> A Phase IV, Prospective, Open Label, Multi-Centre Study of Vorasidenib in Indian Adult and Paediatric Participants 12 Years and Older with Grade 2 Astrocytoma and Oligodendroglioma with a Susceptible IDH1 or IDH2 Mutation following Surgery including Biopsy, Sub-Total Resection, or Gross Total Resection.
7.	Commitments:
a.	I have reviewed the clinical protocol and agree that it contains all the necessary information to conduct the study. I will not begin the study until all necessary Ethics Committee and regulatory approvals have been obtained.
b.	I agree to conduct the study in accordance with the current protocol. I will not implement any deviation from or changes of the protocol without agreement by the Sponsor and prior review and documented approval / favorable opinion from the Ethics Committee of the amendment, except where necessary to eliminate an immediate hazard(s) to the trial Subjects or when the change(s) involved are only logistical or administrative in nature.
c.	I agree to personally conduct and / or supervise the clinical trial at my site.
d.	I agree to inform all trial subject, that the drugs are being used for Investigational purposes and I will ensure that the requirements relating to obtaining informed consent and ethics committee review and approval specified in the New Drugs and Clinical Trials Rules, 2019 and Good Clinical practices guidelines are met.
e.	I agree to report to the Sponsor all adverse experiences that occur in the course of the investigation(s) in accordance with the regulatory and GCP guidelines.
f.	I have read and understood the information in the Investigator's brochure, including the potential risks and side effects of the drug
g.	I agree to ensure that all associates, colleagues and employees assisting in the conduct of the study are suitably qualified and experienced and they have been informed about their obligations in meeting their commitments in the trial.
h.	I agree to maintain adequate and accurate records and to make those records available for audit / inspection by the Sponsor, Ethics Committee, Licensing Authority or their authorized representatives, in accordance with regulatory and GCP provisions. I will fully cooperate with any study related audit conducted by regulatory officials or authorized representatives of the Sponsor.

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i.	I agree to promptly report to the Ethics Committee all changes in the clinical trial activities and all unanticipated problems involving risks to human Subjects or others.
j.	I agree to inform all serious adverse events to the Central Licensing Authority, sponsor as well as the ethics Committee within twenty-four hours of their occurrence. In case, of failure to do so, I shall furnish the reason for the delay to the satisfaction of the Central Licensing Authority along with the report of the serious adverse event.
k.	The report of the serious adverse event, after due analysis, shall also be forwarded by me to the Central Licensing Authority, the Chairperson of the ethics committee and the Head of the institution where the trial has been conducted within fourteen days in accordance with the regulatory requirements.
l.	I will maintain confidentially of the identification of all participating study patients and assure security and confidentiality of study data.
m.	I agree to comply with all other requirements, guidelines and statutory obligations as applicable to clinical Investigators participating in clinical trials.
8.	Signature of Investigator with Date & Stamp:  Investigator Name: Dr. Rimpa Basu Achari Site Name: Tata Medical Center City: Kolkata (Stamp/Seal) 