

To,
Institutional Review Board
Tata Medical Center
14, Major Arterial Road (EW)
New Town Rajarhat Kolkata-700160

Study Title: 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.

Study Number: SER-VOR-001

Subject: Ethics Committee Submission of Study documents for Review & Approval.

Dear Sir/Mam,

With reference to the above-mentioned study, kindly find enclosed the following documents for Ethics Committee review and approval:

Sl. No.	Study Document	Version	Date
1.	SER-VOR-001 Study Protocol	1.0	Dated 24 Apr 2026
2.	Protocol Signature Page	NA	Signed dated 08 Jul 2026
3.	Prescribing Information	NA	Aug 2024
4.	SER-VOR-001 Site specific Informed Consent Form- English	1.0	21 Jul 2026
5.	SER-VOR-001 Site specific Informed Consent Form- Hindi Forward	1.0	22 Jul 2026
6.	SER-VOR-001 Site specific Informed Consent Form- Hindi Backward	1.0	22 Jul 2026
7.	SER-VOR-001 Site specific Informed Consent Form- Hindi	1.0	22 Jul 2026
8.	SER-VOR-001 Site specific Informed Consent Form- Bengali Forward	1.0	22 Jul 2026
9.	SER-VOR-001 Site specific Informed Consent Form- Bengali Backward	1.0	22 Jul 2026
10.	SER-VOR-001 Site specific Informed Consent Form- Bengali	1.0	22 Jul 2026
11.	Translation Certificate Site specific Informed Consent Form (Forward, Backward and Final)- Bengali & Hindi	1.0	22 Jul 2026
12.	SER-VOR-001 Site specific Child's Assent Form- English	1.0	21 Jul 2026
13.	SER-VOR-001 Site specific Child's Assent Form- Hindi Forward	1.0	22 Jul 2026
14.	SER-VOR-001 Site specific Child's Assent	1.0	22 Jul 2026

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13.	SER-VOR-001 Site specific Child's Assent Form- Hindi Forward	1.0	22Jul2026
14.	SER-VOR-001 Site specific Child's Assent Form- Hindi Backward	1.0	22Jul2026
15.	SER-VOR-001 Site specific Child's Assent Form- Hindi	1.0	22Jul2026
16.	SER-VOR-001 Site specific Child's Assent Form- Bengali Forward	1.0	22Jul2026
17.	SER-VOR-001 Site specific Child's Assent Form- Bengali Backward	1.0	22Jul2026
18.	SER-VOR-001 Site specific Child's Assent Form- Bengali	1.0	22Jul2026
19.	Translation Certificate Site specific Child's Assent Form (Forward, Backward and Final)- Bengali & Hindi	1.0	22Jul2026
20.	SER-VOR-001 Site specific Parental Informed Consent Form- English	1.0	21 Jul 2026
21.	SER-VOR-001 Site specific Parental Informed Consent Form- Hindi Forward	1.0	22Jul2026
22.	SER-VOR-001 Site specific Parental Informed Consent Form- Hindi Backward	1.0	22Jul2026
23.	SER-VOR-001 Site specific Parental Informed Consent Form- Hindi	1.0	22Jul2026
24.	SER-VOR-001 Site specific Parental Informed Consent Form- Bengali Forward	1.0	22Jul2026
25.	SER-VOR-001 Site specific Parental Informed Consent Form- Bengali Backward	1.0	22Jul2026
26.	SER-VOR-001 Site specific Parental Informed Consent Form- Bengali	1.0	22Jul2026
27.	Translation Certificate Site Specific Parental Informed Consent Form (Forward, Backward and Final)- Bengali & Hindi	1.0	22Jul2026
28.	CV of Dr. Rimpa Basu Achari	NA	08 Jul2026
29.	MRC of Dr. Rimpa Basu Achari	NA	26May 2026
30.	GCP of Dr. Rimpa Basu Achari	NA	02 Jan 2024
31.	Undertaking by the Investigator	1.0	Signed Dated 08 Jul2026
32.	SER-VOR-001 Draft CRF	0.1	24Apr 2026
33.	SER-VOR-001 Draft CTA	0.1	30 Jun 2026
34.	SER-VOR-001 Study Dairy English	1.0	29 Jun 2026
35.	SER-VOR-001 Study Dairy English to Hindi- Forward	1.0	03 Jul 2026
36.	SER-VOR-001 Study Dairy Hindi to English- Backward	1.0	04 Jul 2026
37.	SER-VOR-001 Study Dairy English to Hindi-	1.0	04 Jul 2026

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	Final		
38.	SER-VOR-001 Study Dairy English to Bengali-Forward	1.0	03 Jul 2026
39.	SER-VOR-001 Study Dairy Bengali to English-Backward	1.0	04 Jul 2026
40.	SER-VOR-001 Study Dairy English to Bengali-Final	1.0	04 Jul 2026
41.	SER-VOR-001 Study Dairy-Translation Certificate (Forward, Backward and Final)- Bengali and Hindi	1.0	04 Jul 2026
42.	DCGI Protocol Submission Screenshot	NA	29 Apr 2026

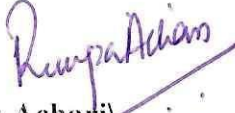
We would like to inform that we will submit below documents to your good office before the SIV:

- DCGI Approval Letter
- Final Study CRF of SER-VOR-001
- Insurance Policy
- CTRI

The study will be conducted as per New Drug Clinical Trial Rules 2019, ICH – GCP guidelines.

Request you to kindly acknowledge the receipt.

Kind regards,


Dr. Rimpa Basu Achari
Principal Investigator
Radiation Oncology

I acknowledge the receipt of above mentioned document on behalf of the Ethics Committee

01/09/2026

Date received



Seal of the Ethics Committee:

Signature



Name of the Personnel