

## Tata Medical Center

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



Date: 01.09.2026

To,  
Head Of The Institute  
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:** HOI 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              |

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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 StudyDairy_English to Bengali-Forward                                              | 1.0 | 03 Jul 2026 |
| 39. | SER-VOR-001 StudyDairy_Bengali to English-Backward                                             | 1.0 | 04 Jul 2026 |
| 40. | SER-VOR-001 StudyDairy_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 Rules2019, 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

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Date received

\_\_\_\_\_

Signature

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Name of the Personnel

Seal of the HOI: