Clinical Trial–Specific Details (To be filled MANDATORILY only if the study is a clinical trial) ***(No editing of form allowed)***

1. **Nature of Clinical Trial**
   ☐ Sponsored
   ☐ Investigator-initiated / Academic
2. **Funding Status**
   ☐ Funded (external sponsor / grant)
   ☐ Intramural / Institutional
   ☐ Unfunded (purely academic)
3. **Study Setting**
   ☐ Single-centre
   ☐ Multicentre – India
   ☐ Multicentre – Global
4. **Type of Intervention**
   ☐ New drug / Investigational New Drug
   ☐ Approved drug – new indication / dose / route
   ☐ Medical device / IVD
   ☐ Standard of Care (SOC) comparison
   ☐ Other (specify): _____
5. **Regulatory Category (as applicable)**
   ☐ Academic Clinical Trial (as per NDCTR 2019)
   ☐ Regulatory Clinical Trial requiring CDSCO permission
   ☐ BA/BE Study
   ☐ Not applicable
6. **Risk Categorisation (based on benefit–risk assessment: refer to IEC SOP)**
   ☐ Minimal risk
   ☐ More than minimal risk
   ☐ High risk

Brief justification:

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7. **Sponsor / Sponsor-Investigator Responsibility**
   ☐ External Sponsor identified
   ☐ Investigator acting as Sponsor-Investigator (academic trial)

8. **SAE Reporting and Management**
   - I confirm that provisions for **identification, immediate medical management, and reporting of Serious Adverse Events (SAEs)** are described in the protocol and shall be followed in accordance with applicable regulations.
   - SAE reporting shall be undertaken within prescribed timelines to the **IEC, Sponsor (if applicable), and Competent Authority**, as required.
   - Please choose who will bear the cost of SAE management in the event an adverse event is reported:

     * External Sponsor:_____
     * Investigator/PI: _____

9. **Compensation & Financial Responsibility (if applicable)**

   ☐ Insurance/indemnity available as per CTA
   ☐ Investigator (academic/non-funded trial)

10. **Declaration by Investigator**
    I hereby declare that for the proposed clinical trial, a clear plan for identification, immediate medical management, documentation, and reporting of Serious Adverse Events (SAEs) has been incorporated in the protocol as per ICMR Guidelines, NDCTR 2019, and ICH-GCP. I confirm that any SAE occurring during the conduct of the study shall be:

- **Promptly identified and medically managed at no cost to the participant**,
- **Reported to the Institutional Ethics Committee and other concerned authorities within prescribed timelines**, and
- **Subjected to causality assessment by the IEC**, in accordance with applicable regulatory requirements.

I further acknowledge that regulatory provisions relating to SAE reporting and compensation, where applicable, shall prevail irrespective of the academic nature, funding status, or standard-of-care nature of the study, and that I shall comply with the decisions and recommendations of the IEC and the institution in this regard.

Signature of Investigator with seal: _____