

Institutional Ethics Committee [IEC]
Super Speciality Paediatric Hospital & Post Graduate Teaching Institute
Sector-30, Noida, Gautam Budh Nagar, U.P.[201303]

Undertaking by the Principal Investigator

- 1. Name of the project:**

- 2. Name, designation and department of the principal investigator:**

- 3. Other members of the research team:**

- 4. Name and address of any other medical college, hospital or institution where parts of the study will be done:**

- 5. Number of ongoing projects/clinical trials in which you are PI: _____**
 - a. Number of sponsored clinical trials with active enrolments: _____**
 - b. Number of sponsored clinical trials with follow up only: _____**
 - c. Total number of ongoing projects (any) (Projects+a+b): _____**

1. I confirm that I will initiate the study only after obtaining all regulatory clearances.
2. I will not implement any deviation from the approved protocol without prior consent of the sponsor nature and it will be intimated to the IEC at the earliest.
3. I confirm that the Co-PI and other members of the study team have been informed about their obligations and are qualified to meet them.
4. I will personally supervise the study and ensure that requirements of obtaining informed consent and other ethical requirements under national regulatory and ICMR guidelines are adhered to.
5. I will maintain accurate and complete record of all cases in accordance with GCP provisions and make them available for audit/inspection by IEC, regulatory authorities, sponsors or their authorized representatives.

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6. I will inform the IEC and the sponsors of any unexpected or serious adverse event at the earliest and definitely within seven days of its occurrence.
7. I will maintain confidentiality of the identity of all participating subjects and assure security and confidentiality of study data.
8. I and my colleagues will comply with statutory obligations, requirements and guidelines applicable to such clinical studies.
9. I will inform IEC if there is change in funding agency/status.
10. I will inform IEC of the date of starting the study within 2 weeks of initiation of the trial and submit annual progress reports and final report to Member Secretary, IEC within 4 weeks of the due date.

Signature of PI

Name _____

Date _____