

**AN4-V1/KSSSCISOP 03/V1**

**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.
6. I will inform the IEC and the sponsors of any unexpected or serious adverse event at

the earliest and definitely as per the national regulatory guidelines.

7. I will maintain confidentiality of the identity of all participating Participants 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** \_\_\_\_\_

**Department** \_\_\_\_\_