#### 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:\_\_\_\_\_\_\_**
   1. **Number of sponsored clinical trials with active enrolments:**
   2. **Number of sponsored clinical trials with follow up only:**
   3. **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 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**