Annexure 10

NETAJI SUBHAS MEDICAL COLLEGE & HOSPITAL, BIHTA, PATNA

UNDERTAKING BY THE PRINCIPAL INVESTIGATOR

1. **NAME AND CODE NUMBER 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 YOY ARE PI.**

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 ICMR and National Regulatory 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 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 Principal Investigator Date