



## **Annexure-II**

### **Undertaking by Principal Investigator**

1. Name of the Project:
2. Name of the Principal Investigator:
3. Designation & Department:
4. Details of Co-PI:
5. Name & address of other organization where study will be conducted:
6. Funding / Sponsor:
7. Detail of other ongoing studies in which you are PI:
  - I confirm that I will initiate the study only after obtaining all the necessary approvals.
  - I will not implement any deviation from the approved protocol.
  - In case of any deviation, I will inform to the IEC at the earliest
  - I confirm that the Co-PIs have been informed about their roles in the study and they possess adequate qualification and skills to pursue their respective roles.
  - I will personally supervise the study and ensure that requirement of obtaining informed consent form and other ethical conditions are met.
  - I will maintain accurate and complete record of all the samples and will be made available for monitoring by appropriate body.
  - I will inform about any serious side effect (SAE) to the IEC as well as funding agency / sponsors at the earliest.
  - I will maintain confidentiality of all the study participants and assure the security and confidentiality of the study data.
  - I and my Co-PIs will comply with related statutory guidelines regarding the study.
  - I will inform to the IEC regarding commencement of the study within 15 days and submit the annual / final report to the Member-Secretary IEC within 15 days of the due date.

**(Signature of the Principal Investigator)**

**Date:**