



## **ALL INDIA INSTITUTE OF MEDICAL SCIENCES, RAJKOT (GUJARAT)**

### **DECLARATION BY THE PRINCIPAL INVESTIGATOR**

**I hereby declare that:**

1. The study will be done as per ICMR/GCP guidelines.
2. The study has not been initiated and shall be initiated only after ethical clearance.
3. Voluntary written consent of the volunteers/patients will be obtained.
4. In case of children and mentally handicapped volunteers/patients, voluntary written informed consent of the parents/guardians will be obtained.
5. The probable risks involved in the study will be explained in full to the subjects/parents/guardians in their own language.
6. Volunteers/patients/parents/guardians will be at liberty to opt out of the study at any time without assigning reason.
7. I will terminate the study at any stage, if I have probable cause to believe, in the exercise of the good faith, skill and careful judgement required for me that continuation of the study/experiment is likely to result in injury/disability/death to the volunteers/subject.

**Date:**

**Name & Designation of Principal Investigator:**

**Signature of Principal Investigator:**