Annexure 6
Investigators Declaration

- This research project (including collection of blood or tissues samples for research) will not be started until the final approval of the IEC has been obtained.
- Research proposal involving human subjects will be done strictly with the schedule Y (Drugs & Cosmetics Act 1940), ICH-GCP and ICMR ethical guidelines, 2006. Research Protocol will not be modified.
- A properly informed and understood consent for all trial subjects will be obtained before their inclusion in the consent form approved by the IEC. Participants will receive an 'information sheet' with details the project design in simple understandable language.
- All serious adverse events associated with the trial report will be reported within a week to the IEC. In the event of a death of the trial subject, the secretary, IEC will be informed within 24 hours.
- Submit status report at least quarterly/midway (whichever is shorter) of the trial. A final report will be submitted at the end of the trial.
- Full details on funding and a proposed budget are included with the trial proposal. The proposed budget is presented on the specific budget sheet of this form.
- We understand that the IEC is concerned about transparent financial transactions during the trial. A report on how the trial funds were utilized will be presented to the IEC along with the final project report at the end of the trial.
- 5% of the total budget will be deposited to IEC PIMS as professional charges for clinical services. This will not apply to projects sponsored by PIMS.
- The investigators will declare any financial gain from the commercial sponsor and any conflict of interest in the drug or product by way of consultations, shareholding etc.
- All data collected during the research project, including those supported by commercial sponsors (e.g. Pharmaceutical company), will remain the property PIMS.
- The study documents will be made available to members of the IEC any time for random verification and monitoring. The study documents must be archived for 5 years post study completion or until the sponsor confirms that the records are no longer required.
- All the findings and conclusions of the proposed project such as review of records, analysis of forms of treatment, investigations, etc will be first presented to IEC PIMS before they are published elsewhere.
- The publication of the project will be submitted with IEC PIMS.
- We the investigators of the proposal trial have read all the statement listed above agree to observe / undertake these IEC required while conducting our proposal project / trial.

Signature of All Investigators