Dr. RAM MANOHAR LOHIA INSTITUTE OF MEDICAL SCIENCE, LUCKNOW

Undertaking by the Principal Investigator/Chief Guide

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 you are PI.

a) I confirm that I will initiate the study only after obtaining all regulatory clearances.
b) I will not implement any deviation from the from the approved protocol without prior consent of the sponsor nature and it will be initiated to the **IEC** at the earliest.
c) I confirm that the CO PI and other member of the study team have been informed about their obligations and are qualified to meet them.
d) 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.
e) I will maintain accurate and complete record of all case in accordance with GCP revisions and make them available for audit/ inspection by **IEC**, regulatory authorities, sponsors or their authorized representatives.
f) I will inform the **IEC** and the sponsors of any unexpected or serious event at the earliest and definitely within seven days of its occurrence.
g) I will inform the **IEC** of any protocol deviation, amendment and any revised information at the earliest and definitely within seven days of its occurrence.
h) I will maintain confidentiality of the identity of all participating subjects and assure security and confidentiality of study data.
i) I and my colleague will comply with statutory obligations, requirements and guidelines applicable to such clinical studies.
j) 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