

Appendix F

UNDERTAKING BY ALL THE INVESTIGATORS

01. Title of the protocol :
02. We the undersigned authors of the above said protocol declare that we will initiate the study only after obtaining all regulatory clearances.
03. We will not implement any deviation from the approved protocol without prior consent of the sponsor nature and it will be intimated to the IERB at the earliest.
04. We 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.
05. We will maintain accurate and complete record of all cases in accordance with GCP provisions and make them available for audit/inspection by IERB, Regulatory authorities, Sponsors or their authorized representatives.
06. We will inform the IERB and the Sponsors of any unexpected or serious adverse event at the earliest and definitely within seven days of its occurrence.
07. We will maintain confidentiality of the identity of all participating subjects and assure security and confidentiality of study data.
08. We will inform IERB of the date of starting the study within 2 weeks of initiation of the trial and submit progress reports and final report to Member Secretary, IERB within 4 weeks of the due date.
09. We further declare that we do not have any conflict in the order of authorship that is submitted for ethical approval. If the necessity arises for change in the order of authorship, we will obtain a written consent from IERB

Investigators name

- 1.
- 2.
- 3.
- 4.

Signature with date

Declaration by HOD

I have no objection in permitting staff / student to conduct research work in the Department.
I take complete responsibility in supervise, produce and present the final research work to the
Institutional Ethical & Review board

Signature, Seal & date