

Sample format of Investigators Undertaking

On departmental letter head

Investigator Undertaking

I _____ Principal investigator for the study, Protocol no. _____ Version _____ date _____ entitled, “ _____ ” assure you that

- 1) In case of a trial related injury or death occurring to the trial participant during the academic clinical trial, free medical management shall be given as long as required or till such time it is established that the injury is not related to the clinical trial, whichever is earlier. In addition, financial compensation will be provided to the participant / nominee (in case of death) if the trial related injury is proven to be related to the study drug or trial procedure.
- 2) In event of negligence by the principal investigator and study team if the trial participant encounters trial related injury or death during the clinical trial, free medical management shall be given as long as required or till such time it is established that the injury is not related to the clinical trial, whichever is earlier. In addition, financial compensation will be provided to the participant / nominee (in case of death) if the trial related injury is proven to be related to the study drug or trial procedure.

This provision of free treatment and financial compensation must be provided by the Principal Investigator in the event of both the clauses mentioned above.

Name of the Principal Investigator: _____

Designation: _____

Signature of the Principal Investigator: _____ **Date:** _____

Seal _____