APPENDIX XII [Schedule Y]

Compensation in case of injury or death during clinical trial:

(1) In the case of an injury occurring to the clinical trial subject, he or she shall be given free medical management as long as required.

(2) In case the injury occurring to the trial subject is related to the clinical trial, such subject shall also be entitled for financial compensation as per order of the Licensing Authority defined under clause (b) of Rule 21 and the financial compensation will be over and above any expenses incurred on the medical management of the subject.

(3) In the case of clinical trial related death of the subject, his/her nominee(s) would be entitled for financial compensation as per the order of the Licensing Authority defined under clause (b) of Rule 21, and the financial compensation will be over and above any expenses incurred on the medical management of the subject.

(4) The financial compensation for clinical trial related injury or death could be in the form of :- (a) Payment for medical management; (b) Financial compensation for trail related injury; (c) Financial compensation to nominee(s) of the trial subject in case of death; (d) Financial compensation for the child injured in –utero because of the participation of parent in clinical trial.

(5) The Sponsor or his representative, whosoever had obtained permission from the Licensing Authority for conduct of the clinical trial shall provide financial compensation, if the injury or death has occurred because of any or the following reasons, namely: -

- Adverse effect of investigational product(s);
- Any clinical trial procedures involved in the study;
- Violation of the approved protocol, scientific misconduct or negligence by the Sponsor or his representative or the Investigator;
- Failure of investigational product to provide intended therapeutic effect;
- Use of placebo in a placebo controlled trial;
- Adverse effects due to concomitant medication excluding standard care, necessitated as part of approved protocol;
- Injury to the child in-utero because of the participation of parent in clinical trial.

(6) Procedure for payment of financial compensation.

- The Investigator shall report all serious and unexpected adverse events to the Licensing Authority as defined under clause (b) of Rule 21, the Sponsor or his representative whosoever had obtained permission from the Licensing Authority for conduct of the clinical trial and the Ethics Committee that accorded approval to the study protocol, within twenty-four hours of their occurrence as per Appendix XI.

- The cases of serious adverse events of death shall be examined as under:
  - (A) An independent Expert Committee shall be constituted by the Licensing Authority as defined under Rule 21(b) to examine the cases and recommend to the Licensing Authority for the purpose of arriving at the cause of death and quantum of compensation in case of clinical trial related death.
  - (B) The Sponsor or his representative, whosoever had obtained permission from the Licensing Authority for conducting the clinical trial and the Investigator shall forward their reports on serious adverse event of death after due analysis to Chairman of the Ethics Committee and Chairman of the Expert Committee with a copy of the report to the Licensing Authority as defined under Rule 21(b) and the head of the Institution where the trial has been conducted within ten calendar days of occurrence of the serious adverse event of death.
  - (C) The Ethics Committee shall forward its report on serious adverse event of death after due analysis along with its opinion on the financial compensation, if any, to be paid by the Sponsor or his representative, whosoever had obtained permission from the Licensing Authority as defined under Rule 21(b) for conducting the clinical trial, to the Chairman of the Expert Committee with a copy of the report to the Licensing Authority within twenty one calendar days of the occurrence of the serious adverse event of death.
  - (D) The Expert Committee shall examine the report of serious adverse event of death and give its recommendations to the Licensing Authority for the purpose of arriving at the cause of the adverse event within thirty days of receiving the report from the Ethics Committee, and the expert committee while examining the event, may take into consideration, the reports of the Investigator, Sponsor or his representative whosoever had obtained permission from the Licensing Authority for conducting the clinical trial and the Ethics Committee.
  - (E) In the case of clinical trial related death, the Expert Committee shall also recommend the quantum of compensation to be paid by the Sponsor or his representative, whosoever had obtained permission from the Licensing Authority as defined under Rule 21(b) for conducting the clinical trial.
  - (F) The Licensing Authority shall consider the recommendations of the Expert Committee and shall determine the cause of death and pass orders as deemed necessary.
  - (G) In case of clinical trial related death, the Licensing Authority, after considering the recommendations of the Expert Committee, shall decide the quantum of compensation to be paid by the Sponsor or his representative, whosoever had obtained permission from the Licensing Authority for conducting the clinical trial and shall pass orders as deemed necessary within three months of receiving the report of the serious adverse event.
  - (H) In cases of serious adverse events, other than deaths, shall be examined as under:
    - (A) The Sponsor or his representative, whosoever had obtained permission from the Licensing Authority for conducting the clinical trial, and the Investigator shall forward their reports on serious adverse event, after due analysis, to the Licensing Authority as defined under Rule 21(b), Chairman

of the Ethics Committee and the head of the Institution where the trial has been conducted within ten calendar days of occurrence of the serious adverse event.

- (B) The Ethics Committee shall forward its report on the serious adverse event, after due analysis along with its opinion regarding the financial compensation, if any, to be paid by the Sponsor or his representative, whosoever had obtained permission from the Licensing Authority as defined under Rule 21(b) for conducting the clinical trial, to the Licensing Authority within twenty one calendar days of occurrence of the serious adverse event.
- (C) The Licensing Authority shall determine the cause of injury and pass order as deemed necessary. The Licensing Authority shall have the option to constitute an independent Expert Committee, wherever considered necessary, to examine such serious adverse events of injury, which will recommend to the Licensing Authority for arriving at the cause of the injury and also the quantum of compensation in case of clinical trial related injury, to be paid by the Sponsor or his representative whosoever had obtained permission from the Licensing Authority as defined under Rule 21(b) for conducting the clinical trial.
- (D) In case of clinical trial related injury, the Licensing Authority, shall decide the quantum of compensation to be paid by the Sponsor or his representative whosoever had obtained permission from the Licensing Authority for conducting the clinical trial and shall pass orders as deemed necessary within three months of receiving the report of the serious adverse event.

- (I) The sponsor or his representative, whosoever had obtained permission from the Licensing Authority for conducting the clinical trial shall pay the compensation in case of clinical trial related injury or death as per the order of the Licensing Authority as defined under Rule 21(b) within thirty days of the receipt of such order.