APPENDIX VIII

ETHICS COMMITTEE

1. The number of persons in an Ethcis Committee should have atleast seven members. Ethics Committee should appoint, from among its members, a Chairperson (who is from outside the institution) and a Member Secretary. Other members should be a mix of medical/non-medical, scientific and non-scientific persons, including lay public, to reflect the different viewpoints.

For review of each protocol the quorum of Ethics Committee should be atleast 5 members with the following representations:

(a) basic medical scientists (preferably one pharmacologist).

(b) clinicians

(c) legal expert

(d) social scientist / representative of non-governmental voluntary agency / philosopher / ethicist / theologian or a similar person

(e) lay person from the community.

In any case, the ethics committee must include at least one member whose primary area of interest / specialization is nonscientific and at least one member who is independent of the institution / trial site. Besides, there should be appropriate gender representation on the Ethics Committee. If required, Subject experts may be invited to offer their views. Further, based on the requirement of research area, e.g. HIV AIDS, genetic disorders etc. specific patient groups may also be represented in the Ethics Committee as far as possible.

Only those Ethics Committee members who are independent of the clinical trial and the Sponsor of the trial should vote / provide opinion in matters related to the study.

2. *Format for Approval of Ethics Committee*

To

Dr.

Dear Dr. _____

The Institutional Ethics Committee / Independent Ethics Committee (state name of the committee, as appropriate) reviewed and discussed your application to conduct the clinical trial entitled "....." on .....(date).

The following documents were reviewed:

(a) Trial Protocol (including protocol amendments), dated_____ Version no (s)._____

(b) Patient Information Sheet and Informed Consent Form (including updates if any) in English and/or vernacular language.

(c) Investigator's Brochure, dated_____, Version no._____

(d) Proposed methods for patient accrual including advertisement (s) etc. proposed to be used for the purpose.

(e) Principal Investigator's current CV.

(f) Insurance Policy / Compensation for participation and for serious adverse events occurring during the study participation.

(g) Investigator's Agreement with the Sponsor.

(h) Investigator's Undertaking (Appendix VII).

The following members of the ethics committee were present at the meeting held on (date, time, place).

_____ Chairman of the Ethics Committee

_____ Member secretary of the Ethics Committee

_____ Name of each member with designation

We approve the trial to be conducted in its presented form.

The Institutional Ethics Committee / Independent Ethics Committee expects to be informed about the progress of the study, any SAE occurring in the course of the study, any changes in the protocol and patient information/informed consent and asks to be provided a copy of the final report.

Yours sincerely,

Member Secretary, Ethics Committee.