



आयुर्वेद शिक्षण एवं अनुसंधान संस्थान

Institute of Teaching and Research in Ayurveda

राष्ट्रीय महत्व का संस्थान, आयुष मंत्रालय, भारत सरकार

Institute of National Importance, Ministry of Ayush, Government of India

Website: <https://itra.ac.in> Email: ethics@itra.edu.in

Format for Approval of Ethics Committee

To,

Dear Dr.

The Institutional Ethics Committee 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.

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 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