

(SPONSORED BY : CHANDRAMMA EDUCATIONAL SOCIETY)

Affliation to Kaloji Narayanarao University of Health Sciences, Warangal, Telangana.

Reconginsed by Dental Council of India, New Delhi

No. MRDCW/ Policy/ JUNE-2020/01

INSTITUTIONAL ETHICAL COMMITTEE

I herewith constitute **Institutional Ethics Committee** with the following members. The Roles& Responsibilities of the Council are enclosed.

Roles & Responsibilities of Institutional Ethics Committee

- 1. The basic responsibility of an IEC is to ensure protection of the dignity, rights, safety and well-being of the research participants.
- 2. Membership of the IEC is position of responsibility and the members are expected to approach this position with the seriousness and professionalism befitting their role in aiding the advancement of science and protection of research participants.
- 3. IEC members are expected to show interest and motivation, commitment and availability, experience with or education regarding the science and ethics of research.
- 4. IEC members should attend a minimum of 70% of the meetings every year and should inform the member secretary at least one week in advance if they are unable to attend an IEC meeting.
- 5. IEC members should attend the trainings conducted for the members with in IEC.
- 6. Every new member will get trained on all of the above-mentioned guidelines (Indian GCP, ICMR, and ICH-GCP) and rules at the time of appointment.
- 7. When a new rule/ guideline/ supervision is happened, all the members would be trained and training record would be maintained for the same.
- 8. Members should inform the secretary in advance if they anticipate being unavailable for three consecutive meetings.
- 9. Will review all the research protocols submitted to them with in specified time limits.

- 10. Are conducted under the supervision of appropriately qualified medical personnel with the required expertise.
- 11. All members should maintain absolute confidentiality of all discussions during the meeting and sign a confidentiality form and expected to declare competing conflicts of interest with respect to research proposals or Investigators if any.
- 12. IEC members are requested to sign a confidentially agreement on joining and this will renewed with every extension.
- 13. Members should submit an updated CV on joining the IEC and with every extension.
- 14. Members should return all materials (research documents) to the secretary after the meeting and they are not permitted to make copies of any these materials.
- 15. IEC ensures the safety, rights and well-being of all trial subjects. Special attention will be paid to trials that may include vulnerable subjects (children, pregnant and nursing mothers, geriatric subjects, disabled subjects and minorities).
- 16. Prime attention and care would be taken to evaluate the safety and well-being when the vulnerable category of subjects participating in a clinical trial. The local regulation in the country would be taken as the standard of evaluation.
- 17. Conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution.
- 18. IEC will conduct continuing review of each ongoing trial at intervals appropriate to the degree of risk to human subjects.
- 19. IEC will ensure that adequate written information is provided in the Inform Consent Form and will ask for additional information to be incorporated in ICF for protection of rights and well-being of the subjects.
- 20. Based on the requirement of research area, for example HIV, genetic disorders etc. specific patient groups may also be represented in the Ethics Committee.
- 21. IEC will review both the amount and method of payment to subjects to assure that they neither present problems of coercion nor undue influence on the trial subjects.
- 22. IEC will ensure that all the information regarding payment, including amounts and schedule of payments to trial subject to be informed to IEC.

