

- A Report -  
**Institutional Review Committee - Appraisal Meeting**  
Held at Kerala Sahithya Academy, Vylloppilly Hall, Thrissur  
On 08/06/2011- 5.30 P.M



The conduction of clinical drug trials in India poses many challenges. Many pharmaceutical companies outsource their drug trials to India because of lower cost, large population in combination with poverty and numerous diseases along with weak legal mechanism to curb the unethical trials. The participants of drug trials are often illiterate, poor and ignorant about their rights which lead to the unscrupulous exploitation by those who conduct the trials. While conducting the study on clinical drug trials in Kerala we found that the mandatory norms and best practices in clinical drug trials were rampantly violated. One of the main reasons for occurrence of the violation of the participant's rights is malfunctioning of the Institutional Review Board. We realized that the committee members are not aware of their duties and responsibilities. At present, the ethical rightness of a clinical drug trial depends wholly on the integrity and independence of institutional ethics committee which is supposed to be the guardian for protecting the rights of human participants.

In this context, during the second phase of our study we propose to conduct quarterly workshops for the members of the ethics committee on best practices and to evaluate the present functioning of Ethics committees. One quarterly




workshop in this regard was held at 5.30 P.M on 8<sup>th</sup> June, 2011 at Vylloppilly Hall, Kerala Sahitya Academy, and Thrissur. Chairperson and Members of Institutional Review Board of Medical colleges and other leading hospitals participated in the workshop. Adv. George Pulikuthiyil, Executive Director Jananeethi welcomed the invited guests and dignitaries. Program co-coordinator Adv.Sunilkumar.P explained the purpose of the meeting and mandatory norms with regard to composition and function of ethics committees as provided under Guidelines issued by Indian Council of Medical Research. Participants of the meeting actively took part in the discussion. Doctors especially those who conduct clinical drug trials appreciated Jananeethi's initiative and asserted its importance. They had promised their cooperation and support for ensuring the conduction of clinical drug trials ethically sound and corruption free. One of the shocking but expected facts revealed during the meeting was the complete ignorance among some ethical committee members about their role and responsibilities as a member of ethics committee.



Another strange thing discovered during the meeting was the interchange of ethical committee members on reciprocity, which will definitely result in conflict of interest and ultimately defeat the very purpose of the committee. On the whole the appraisal meeting was successful in bringing a positive attitude from the stakeholders especially from the doctors who conduct clinical trials and it also exposed the flaws of the present system which requires immediate intervention.

  
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