

GUIDELINES ON CLINICAL TRIAL OF DRUGS FRAMED BY COMMITTEE CONSTITUTED BY THE NATIONAL HUMAN RIGHTS COMMISSION

During its deliberations, the Committee observed that the main concerns of the committee with reference to the violation of human rights, noted in the context of Hyderabad case of 2011, were as follows:-

1. Subjects, who were normal healthy persons participated in the bioavailability/ bioequivalence study without being given proper information of the risks involved in the study,
2. Participants were exploited for money.
3. Participants in the study were not provided proper medical care for subsequent side effects.

The Committee noted that an Expert Committee on Reforms in drug regulation and clinical trials has been formed by the MOHFW Govt. of India under the chairmanship of Dr. Ranjit Roychaudhary. The Committee also noted that notifications, rules and regulations, additions, deletions to the Drugs and Cosmetics Act and Rules are being issued from time to time including the recent ones on :-

- a. compensation in case of injury or death during clinical trial, rule 122 DAA of 30.1.2013,
- b. registration of Ethics committee rule 122 DD of 8.2.2013 and
- c. permission to conduct clinical trial 122 DAC of 1.2.2013.

The Committee recommended that all institutions and ethics committee should implement within the time frame, stipulated in the Act, these and such changes in the Act and Rules that are brought about from time to time.

3. The Committee has suggested that :-
 - a. Ethics committees should be set up in all institutions undertaking studies on human subjects and should be registered as per the Act.
 - b. Standard Operating Procedure (SOP) should be written down and followed in all clinical trials/ clinical studies, based on prevailing good clinical practices (GCP) guidelines issued by CDSCO, ICMR ethical guidelines for biomedical research on human participants, Act and Rules.

There should be an effective mechanism for monitoring the implementation of the SOPs.

4. Ethics committees should be constituted as per Act, Rules and regulations. All ethics committee members should familiarise themselves with various aspects of ethics guidelines and provisions of Act, rules etc for clinical trials.

5. It is necessary to set up Regional/State training centres with ethics committees of their region/state allocated to them and develop a common minimum syllabus for the course. Attendance in the course could be then made compulsory for persons becoming eligible to be elected members of Institutional Ethics Committees. Continuing education program on ethics should be also organized at these centres and participation for IEC Members made mandatory. Adequate budgetary provisions will be necessary to support travel etc of non-official members of these Committees for attending these courses.

Implementation should be monitored.

6. Informed consent procedure should be standardised and simplified. Information given to the patient should include details of risks involved as per the current knowledge. It should also inform about the rights of the participants for

compensation in case of injury or death during the study as per the prevailing provisions of Act and rules, regulations.

In addition to the written patient information sheet, an informative, audio video CD by the investigator may be prepared, shown and given to participants specially if study is being done on illiterate subjects with a proof of their having seen and received it.

7. Procedure for recruitment of participants/volunteers for the trial should be documented in the SOP. Guidelines for the procedure should be framed with due deliberation and discussion and should be in consonance with ethical guidelines for biomedical research.

8. Investigator should ensure adherence to Medical Council of India code of ethics specially for research as stated in chapter 7 and for Human rights as stated in chapter 6.

9. Participants of the clinical trial should be provided medical care from the time of enrolment in the study, for the duration of study and for the period of follow up as specified in the protocol. How and where it will be available, including close to the participants residence should be specified in the patient information sheet.

10. In the Drug and cosmetics Act and Rules, definition of clinical trial varies in different Rules, schedules and appendices.

Notification of 30.1.2013 for compensation is given as rule 122 DAB to be inserted after 122 DAA. It needs to be clarified whether rule 122DAB pertains to only clinical trials of new drugs.

As per Drugs and cosmetic Rules 1945, part X-A, import or manufacture of new drug for clinical trials or marketing. 122 DAA : defines clinical trial as systematic study of new drug

(new chemical entity, new indication, new formulation etc)
Schedule Y pertains to New drug.

However Appendix XXXIII, clinical trial registry specifies that all interventional trials should be registered. (All interventional clinical trials conducted in India and involving Indian participants need to be registered. An interventional clinical trial is any research study that prospectively assigns people to one or more health related interventions (e.g., preventive care, drugs, surgical procedure, behavioural treatments, etc) to evaluate their effects on health related outcomes. Thus, early and late trials, trials of marketed or non marketed products, randomized or non randomized trials - all should be registered.)

Appendix XXXVIV, GCP guidelines for clinical trials in India and

Appendix XXXVIII, Guidelines for BA/BE studies define Clinical Trial (Clinical study) as a systematic study of pharmaceutical product on human subject(s) - (whether patients or non-patient volunteer) - in order to discover or verify the clinical, pharmacological (including pharmacodynamic/ pharmacokinetics), and/or adverse effects, with the object of determining their safety and/or efficacy.

11. It is necessary to have an uniform definition of which type of clinical studies will be considered clinical trial.