

Registration of Ethics Committees to become mandatory for clinical trials

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After two years of making the registration of clinical trials mandatory, the union health ministry will soon make the registration of Ethics Committees attached with the Clinical Trial Organisations mandatory.

According to sources, a decision to this effect was taken by the Drugs Technical Advisory Board (DTAB), the highest decision-making body under the Union health ministry on technical matters, which held its comprehensive meeting on October 10 under the chairmanship of Director General of Health Services (DGHS), who is the ex-officio chairman of the Board.

The DTAB's decision to make registration of Ethics Committees mandatory comes in the wake of widespread complains that the Ethics Committees at most of the clinical trial sites are not independent and also not active with no monitoring of the trials. So far, only the registration of clinical trials with the Drugs Controller General of India (DCGI) is mandatory in the country. Independent ethics committees are constituted by the individual companies and it is not registered. For starting any clinical trial, the approval of the ethics committee is crucial as without which the DCGI will not provide his sanction for beginning the study in the country.

There should be at least five members in the ethics committee, consisting of a doctor, preferably a pharmacologist, a lawyer, an atheist, a housewife and a scientist. All of them should be provided training in good clinical practices (GCP) to get a firsthand knowledge about the clinical activities.

According to sources, with the cases of trial related deaths and injuries registering a steady increase in the country, the health ministry wanted to streamline the clinical trial sector which by and large remains unregulated in the country.

Sources also said that the immediate provocation for the ministry to further streamline the clinical trial sector is the recent irregularities reported in conducting of clinical trials by Axis Clinicals, a Hyderabad based CRO in which the company is alleged to have conducted clinical trials of a breast cancer drug on nearly 30 illiterate agriculture labourers after luring them with Rs.10,000 each.

Subsequently, the investigations by the DCGI had revealed various irregularities in conduct of the studies by the company with respect to subject recruitment process, informed consent process, independence of the Ethics Committee and its review and decision making process.

Sources said that DTAB at its meeting on October 10 examined the issue in detail and decided to make the registration of Ethics Committees mandatory.

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