Title: Accreditation of Ethics Committees: Few Comments and Suggestions !

Authors with affiliations:

Dr Sachin M Satpute,

Assistant Professor, Department of Pharmacology, Topiwala National Medical College & B Y L Nair Ch. Hospital, Mumbai Central, Mumbai-400008. Also, member pharmacologist, Institutional Ethics Committee, Prince Aly Khan Hospital, Mazgaon, Mumbai.

Dr Vihang S Chawan,

Associate Professor, Department of Pharmacology, Topiwala National Medical College & B Y L Nair Ch. Hospital, Mumbai Central, Mumbai-400008. Also, Secretary, Institutional Ethics Committee, Topiwala National Medical College & B Y L Nair Ch. Hospital, Mumbai Central, Mumbai-400008.

Mailing address: Department of Pharmacology, College Bldg., 2nd floor, Topiwala National Medical College & B Y L Nair Ch. Hospital, Dr A L Nair Road,Mumbai Central, Mumbai-400008

Email address: [drsachinsatpute@yahoo.com](mailto:drsachinsatpute@yahoo.com)

Competing interest: Nil

Funding support: Nil

Recently 1st draft of document with 1st edition November 2014 titled “Accreditation Standards for Clinical Trials Ethics Committee, Investigator and Clinical Trial Site” was released on by National Accreditation Board for Hospitals and Healthcare Providers (NABH). It gives the criteria to be followed for accreditation of Ethics Committee (EC), Investigator and the sites where clinical trials are to be carried out. In this document there are 3 sections. The section 1 deals with the accreditation of Ethics Committees. The section 1 has 10 standards and 43 objective elements. The section 2 deals with the accreditation of investigator. The section 2 has 8 standards and 25 objective elements. While section 3 deals with the accreditation of clinical trial site. The section 3 has 6 standards and 26 objective elements.

Section 1 deals with the accreditation of both independant ethics committee for bioavailability/bioequivalence (BA/BE) studies and institutional EC for clinical trials. The objective of this section is that EC is adequately qualified, experienced and knowledgeable in ethical issues and applicable rules and regulations for conduct of clinical trials ensuring scientific integrity and protection of subject rights, safety and wellbeing.

Out of 10 standards of section 1, standard 1.2 deals with the ‘Standard Operating Procedures (SOPs): The Ethics Committee has and follows written SOPs for its different functions as per applicable rules and regulations.’ Under this, 1.2.2 states about the list of mandatory procedures for Ethics Committee which includes policy regarding training for new and existing committee members. Here, we feel it would be prudent if this document clarify who is the authorised trainer? The eligibility of trainer with respect to qualification and experience should be clarified. Nowdays, various clinical research organizations (CRO) and academic institutions conduct GCP training workshops. The content of such training needs to be defined and should be uniform. The duration of training in terms of the number of hours also needs to be defined. The pre and post assessment during such workshops to assess the knowledge gained is highly recommended. In fact, it would be prudent if the regulatory authority conduct such standardized training workshops at regular intervals at various centres in India.

Standard 1.6 deals with the ‘Review Process: The Ethics Committee follows documented procedures for initial review of the trial related documents, review of amendments and periodic review.’ Under this, 1.6.1 states that the investigator conducts only three trials at a time. It would be prudent if the document clarify whether academic trials like dissertation/thesis are also included under this category. As some investigators working as Post-Graduate (PG) student guide have 2-3 students at a time doing their thesis. It would be difficult for such investigators to restrict to only three trials at a time.

In other words, it means that the investigator can take up the fourth trial if one of these three trial is completed. Hence this document should give the definition of ‘completed’ trial. Is it that the recruitment is completed or clinical trial report is submitted to the regulatory authority or the regulatory authority gives permission to market the investigational product. These issues needs appropriate clarification.

Standard 1.8 deals with the ‘Monitoring: The Ethics Committee follows documented procedures for monitoring and for cause assessment.’ How many ECs are monitoring clinical trials currently? Are EC members trained currently for monitoring clinical trials? How many ECs prepare monitoring report? We feel monitoring of clinical trials in a neglected area by most of the ethics committees. Hence, regulatory authority should provide training to EC members for monitoring of clinical trials. All these members will have to put an extra effort and time to do monitoring. As monitoring is a complex process which involves but not limited to the activities like checking various documents like informed consent documents, EC/ Regulatory authority approval letters, case record forms (CRF), various source documents and other documents generated during the conduct of the clinical trial. It also includes monitoring of investigational product handling with its proper storage and all other processes mentioned in the clinical trial protocol. In a single EC meeting, more than one protocols can be discussed but monitoring of clinical trials can not be done in a single day. It is an ongoing process. This process will involve multiple days for multiple trial projects at various stages at appropriate intervals. A small monitoring committee can be formed involving mainly scientific members/ pharmacologist with monitoring background who can take the responsibility of monitoring of clinical trials.

Standand 1.9 deals with the ‘Self-Assessment: The Ethics Committee has and follows documented procedures for self-assessment.’ This document should define the various components of self-assessment of EC. These components should include various parameters like attendance for the meeting, GCP training, individual contribution in terms of number of relevant queries asked, update of knowledge with respect to ethics and regulatory updates, administrative support like receipt of documents for review on time, maintainance of minutes of meeting, record keeping, monitoring of trials and other components.

As these accreditation efforts are ultimately done with the aim to improve the current system related to the conduct of clinical trials in India. Though above issues needs to be addressed by ethics committees through their standard operating procedures (SOP), making these subjective components objective would help to make these standards uniform. Such clarifications in this document before it becomes guidance in India would add to make this process simple, clear, transparent and uniform.

Abstract:

National Accreditation Board for Hospitals and Healthcare Providers (NABH) recently released the 1st draft of document with 1st edition November 2014 titled “Accreditation Standards for Clinical Trials Ethics Committee, Investigator and Clinical Trial Site”. This document has 3 sections. Section 1 deals with the accreditation of ethics committees (EC). But certain issues are not properly clarified in this draft of document.

The training of EC members should clarify the eligibility of the trainer with respect to its qualification and experience. Restriction of three trials at a time needs appropriate clarification. Also the definition of ‘completed’ trial is needed. Monitoring of clinical trials, an important but neglected area also requires proper training of EC members in current scenario. In self-assessment of ECs certain components needs to be defined and made objective to prevent further loopholes in the system. These changes would help to make the process transparent and uniform in India.