***Type of article-*** Research article

***Title***

Institutional Ethical Committee: A shepherd’s Guidelines

***Abstract****-*

Introduction: Meticulous clinical studies can significantly change dental practice and improve oral health. India offers unique opportunities considering the well trained investigators and renowned dental institutes. The ICMR released certain guidelines in 2006 to meet ethical challenges posed by these advances.

Aim & Objectives: To assess the dental faculty and post graduate students in Haryana on knowledge and attitude regarding their respective institutional ethical committee (IEC).

### Materials & Methods: A self administered questionnaire was provided to the participants regarding the proceedings of their institutional ethical committees.

### Results: Of all the 400 participants, 36% were aware of their IECs and less than 50% were aware of the legislation regarding their registration. Majority of the participants were not aware of the membership requirements, duties and the role of different members of their IEC. Almost all the participants were interested in educating themselves in Bioethics.

### Conclusion: Researchers should be aware of the composition and responsibilities of an IEC to safeguard the welfare of the participants.

### *Keywords*: Ethics Committees, dental research, health facilities, bioethics

**Introduction**

Can professionals escape their moral obligations?

Do clinical researchers allowed to err in human experimentations?

Are we allowed to sacrifice all other human values in the name of scientific research?

Such questions were raised in 1966 in an essay ‘‘Ethics and clinical research’’ where, Henry K. Beecher identified ethical lapses in research carried out by physician–scientists in renowned universities and published in the world’s leading journals. Through his essay(1), Beecher not only prompted a reconsideration of research practices, but also triggered the groundwork for today’s ethical codes and review committees.

Health professionals and research workers may not be able to do what is right in all instances. The need for Institutional Ethics Committee (IECs) in medical and research establishments is a result of this realization, thus affirming human rights as a prerogative to all members of society. Their common main purpose is to ensure that the research is conducted in accordance with guiding ethical principles and that the rights and welfare of research participants are protected.

In India, the constitution of ethics committees (ECs) started with extramurally sponsored research(2). The Indian Council of Medical Research (ICMR) formulated ethical guidelines for biomedical research(3), primarily a guidance document for medical, epidemiological and public health research.

The guidelines provide a Statement of General Principles, emphasizing the need for evaluation of research proposals, mandating that institutions allowing proposals on biomedical research involving human participants should be cleared by an appropriately constituted Institutional Ethics Committee (IEC). The committee is also referred to as Institutional Review Board (IRB), Ethics Review Board (ERB) and Research Ethics Board (REB) in other countries.

In scenarios where the researcher is not associated with an institution or in cases where the institution lacks an ethics committee, an independent committee can also be approached.

These IECs should be multidisciplinary and multisectorial in composition. It is generally accepted that a minimum of five persons is required to form the quorum without which a decision regarding the research should not be taken. The members should be a mix of medical/ non-medical, scientific and non-scientific persons including a subject expert, a social scientist, an ethicist, a legal person and a lay person to represent the differed points of view. The IEC should appoint from among its members a Chairman who should be from outside the Institution and not head of the same Institution to maintain the independence of the Committee. The Member Secretary should be from the same Institution and should conduct the business of the Committee. Every IEC should have its own written Statement of Purpose (SOP) made available to each member according to which the Committee should function.

The IEC should meet periodically at frequent intervals to review new proposals, evaluate annual progress of ongoing ones, review serious adverse event reports and assess final reports of all research activities. Thus, even after the initial review of the proposed research protocols prior to initiation of the projects is completed, the IEC is entrusted with the responsibility of regular monitoring of the approved programmes to foresee the compliance of the ethics during the period of the project.

Unfortunately, even in institutions who take a giant leap with formation of such a committee, there are many a fallouts. Presently, India prides itself on approximately 300 institutions offering Post Graduate (PG) programs in Dental Surgery. Each year more than four thousand PG students carry out various researches in the form of thesis and projects as a part of their curriculum. These numbers are proof of the huge potential that the dental fraternity of our country holds to offer.

However, not only there is a significant divergence with respect to the practices followed by various ECs, there is also a general lack of awareness as regards to the process of ethical approval. The professionals fail to understand that it is inescapable for them to isolate themselves from the members of authority who define and defend their research activities. The obligatory ethical approval is a certificate in name only. The committee in their effort to accomplish scientific breakthrough, fail to apprehend the patient’s interest.

Efforts are being made under active consideration by the Ministry of Health, to set up a Biomedical Research Authority under the proposed Bill on Biomedical Research on Human Participants (Promotion and Regulation) to evaluate and monitor functioning of the IECs through registration with this authority.

On the contrary, the researchers also need to be reoriented towards the committees from whom they seek approval. It was with this concern that the present study was conducted to strengthen the level of health research situation in India.

**Aim:**

To examine the knowledge and attitudes among dental faculty and dental post graduate students in dental institutions affiliated to Pandit B.D. Sharma University of Health Sciences regarding institutional ethical committee.

**Objectives:**

* To prepare a questionnaire to assess the knowledge and attitudes of dental researchers regarding Institutional ethical Committee.
* To assess the knowledge and attitudes of dental faculty and post graduate students of Haryana regarding Institutional ethical Committee.

**Methodology:**

The study was conducted as a descriptive survey of knowledge and attitudes regarding IECs of various dental institutions in the state of Haryana, India.

### A self administered questionnaire (Table 1) was designed based on the ICMR Ethical Guidelines for Biomedical Research to assess the knowledge of respondents regarding the process of constitution, functions, orientation, and evaluation of their respective committees.

The questionnaire was pre-tested for validity before use.

The study population included the dental faculty and post graduate students in dental institutions affiliated to Pandit B.D. Sharma University of Health Sciences.

After obtaining the ethical approval from the institutional ethical committee at SGT Dental College, Hospital and Research Centre, permission was also taken from the participating institutions and verbal consent from the respondents prior to data collection.

Complete anonymity of the participants was maintained. No tracking system was used to determine who responded and who did not.

Questionnaire data was analyzed by statistical software (SPSS 16.0 for Windows, SPSS Inc., Chicago, USA).

**Results**

A hundred percent response rate was observed. Out of 400, twenty nine percent were males and seventy one percent were females.

The mean age of the participants was 33.7 years.

Forty percent participants were MDS faculty whereas sixty percent were PG students.

**Information about IEC**

Fifty two percent of the faculty and nineteen percent of the students were aware of the concept of an ethical committee.

Thirty nine percent and twenty one percent of the faculty and the students, respectively, were not aware whether their IEC was referred to differently, for example, as Institutional Review Board (IRB). On further query, it was found that most of the participants mistook the IEC as the administrative committee of their institution.

**Constitution**

Thirty six percent and seventy eight percent of the faculty and student participants were not aware of the constitutional members of their IEC. They were not aware of the committee’s chairperson and his association with the institution. In certain colleges, the principal was the head of the IEC as opposed to the guidelines. Moreover, the concept of an independent IEC, not in affiliation to the institution was unknown to most of the participants.

Eighty two percent of the faculty was not aware of the constitutional requirements for an IEC. Majority of the faculty had no information of the qualification requirements, if any, for the members of the ECs. Awareness regarding the inclusion of a layman was poor amongst all the participants.

Also, eighty seven percent participants did not know the quorum requirements for research protocol approval.

**Legislation**

More than fifty percent of the participants were not aware of the legislation pertaining to ethical issues or registration of ECs even though ten percent of the participants have participated in conducting clinical trials. Moreover, very few participants were attentive of the recent news event concerning the introduction and the content of the “Biomedical Research Human subjects Promotion and Regulation Bill”.

**Evaluation**

Forty percent of the participants reported the regular evaluation of their research projects, however, majority of the participants were not aware of the person in charge of evaluation of research protocols.

It was however commendable that almost all the participants showed interests in educating themselves in Bioethics.

**Discussion**

The present study was conducted as an attempt to *reorient* theresearch workers towards the proceedings of the committees from whom they seek ethical approval.

It is known that clinical trials in India are guided according to the International Committee of Medical Journal Editors (ICMJE), 2004. The ICMJE requires that all clinical trials be registered, and their design disclosed, in a publicly available register before enrolling participants(4). It is also known that research workers have an obligation to safeguard the interests of the trial participants and plays a major role in trial proposal, monitoring, registration, funding and so forth.

The first survey on IECs in our country was conducted by ICMR-WHO in 2003(2). 1,200 questionnaires were mailed to medical institutions with a response rate of 18.58 %. Unfulfilled constitutional guidelines were evident similar to the present study where majority of the faculty participants did not have any information regarding the professional qualifications required to be appointed as a member of an IEC.

Previously, in an attempt to complement the efforts of the ICMR in strengthening the ECs of various health research institutions in India, Brahme R and Mehendale S(2) in 2007, studied the profile and role of EC members in terms of their knowledge and opinion concerning ethical issues, in various hospitals and institution in Pune. It was evident that even with appropriate constitution, the members had sub-optimal knowledge and understanding regarding ethical issues involving human subjects. In a similar attempt, the present study focussed on spreading awareness on the scope and the role of EC members. Moreover, it is noteworthy to highlight that though 22% of the faculty and 17% of the PG students have participated in conducting clinical trials, surprisingly, their knowledge with respect to the constitution, proceedings and legislations of the ethical committee is very low. Hence, the present study can also be considered as an attempt to generate awareness among the researchers, seeking ethical approval, regarding the proceedings involved with respect to IEC as per the ICMR guidelines.

Taur et al(5) in 2006 determined the extent to which investigators comply with format requirements given in ethical guidelines and regulations. Lack of training schedule of the ECs was evident in his report similar to the present study.

Shetty Y C et al(6) conducted seven site visits in 2008-2009 in Mumbai at various research institutes and identified serious lapses in issues related deviation from protocol, reporting of study progress to the IEC, recruiting additional participants without IEC approval, reporting of serious adverse events and investigator’s lack of awareness. The other common observations included not mentioning the venue and time of the meeting, and not stating the method of patient accrual. These findings draw attention to the current pattern of irregular EC meetings and lack of periodic evaluation of research works still prevalent in various institutions.

Nadig P and colleagues(7), 2011, surveyed the knowledge and attitudes of members of 11 ECs in a South Indian state, towards the practices of their respective committees. The findings of their survey however suggested that there have been some improvements in the functioning of IECs in the past decade. However, even with improvements made on the administrative front, considerable efforts need to be made towards the reorientation of the researchers towards the guiding authority.

**Conclusion**

Ethics plays a central role in health research. Research involving human subjects is based on a moral commitment to achieve human welfare and gain knowledge. On the other hand, clinical research runs the potential risk of causing harm, and therefore the need to establish sound ethical practices is greater than ever before.

This has become more important particularly in India where large numbers of research activities, including clinical trials are being conducted and likely to substantially increase in the coming years.

On the same grounds, it is also necessary to understand and explore the quality and performance of not only the ECs but also the knowledge and attitude of the researchers who seek approval from these committees. Even though the performance of an ethics committee is expected to depend on its appropriate constitution, the role of the researchers should not be ignored.

Generation of opportunities should for continued training in Bioethics and monitoring of university/ state/ national regulatory bodies play a major role in encouraging standardized research activities.

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**Table**

1. Table 1- Questionnaire

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| --- | --- |
| **Topic of interest** | **Questions** |
| Information | **Do you know what IEC refers to?**  **Is the Institutional Ethical Committee and Institutional Review Board same authorities?** |
| Constitution | **Should the chairman of the Institutional Review Board be associated with the Institution?**  **Is the Review Board of your institution an independent committee?**  **Are you aware of the membership requirements in an Institutional Review Board?**  **Can a layman be appointed as a member of the Institutional Review Board?**  **Are you aware of quorum requirements within an Institutional Review Board?** |
| Legislation | **Have you conducted any clinical trial or is there any clinical trial conducted under your supervision?**  **Are you aware of any legislation regarding registration of Institutional Review Board?**  **What is the “Biomedical Research Human subjects Promotion and Regulation Bill” related to?** |
| Evaluation | **Who screens the proposals for completeness and risk evaluation?**  **Is there any protocol for regular follow up of an approved study in your institution?** |

**Figure**

1. Figure 1- knowledge of facylty and students