Original Article

A cross-sectional study: Need of equal respect for all professionals in the Institutional Ethics Committees' composition

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Abstract

Background: The composition of the Institutional Ethics Committee (IEC) with an equal respect plays a major role in evaluating research proposals to ensure the safety of the subjects and ethical quality of research project. It is mandatory that all research projects with an involvement of human subjects should be approved by the IEC before commencement.

Aim: To find out the equality of respect to members of IEC irrespective of nature of their profession.

Materials and Methods: Methods include a cross-sectional study, the general information and member composition, multidisciplinary nature, independent performance, competence, decision capability, professionally biased of IECs in health research institutions of Punjab, India. A structured self-administered questionnaire was developed and provided to all health/research institutions providing the graduate/postgraduate education in medical sciences under the jurisdiction of Baba Farid University of Health Sciences, Faridkot, Punjab, India.

Results: Of the total 142 institutes, only 80 (56% response rate) institutes responded to the questionnaire. Of the 80 institutes which responded, 65 institutes (81.25%) had IEC, while 15 (18.75%) institutes lacked IEC. The compositions of only 22% IECs were in compliance to Drug Controller General of India (DCGI) guidelines and only nine (14%) institutes of the state of Punjab had approval from the DCGI.

Conclusion: Study clearly indicates the carelessness of regulatory bodies and lack of fair practices toward constitution of the IEC. The ratio of nonscientific members (ethicist, philosopher, and layperson) in the IEC composition was incredibly low. This study also reveals the professionally biased and noncompliance with schedule Y guideline in relation to the representation of lawyers, ethicists, and nonscientific members.

Keywords: Drug Controller General of India Approval, Ethics, Indian Council of Medical Research, Institutional Ethics Committee, schedule Y

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INTRODUCTION

The Declaration of Helsinki uniformly requires that all biomedical research involving human participants, including research on identifiable human material or data, should be approved by the Institutional Ethics Committees (IECs).[1] Having evolved out of the scandalous unethical research practices of the mid- and late 20th century, the ethics review of the study protocols, by the IECs, has become the international standard of ethically and scientifically acceptable biomedical research. Today, concerns over the quality of the IEC function are increasing worldwide. Clinical research runs the potential risk of causing harm, and therefore sound standards of ethics must be established to protect research participants.[2] This has become more important in India where large number of clinical trials are being conducted and where such trials are likely to substantially increase in the coming years.[3]

As supported by the revised schedule Y in Amendment 2005 of the Drugs and Cosmetics Act, 1940,[2] schedule Y elaborately sets forth the structure and function of the IEC and gives a detailed explanation of the approval letter. A recent survey by the Indian Council of Medical Research (ICMR) among over 200 institutions reveals the ground reality that many IECs are far from satisfactory in structure and function defined by the council in its revised guidelines of 2000, "Ethical guidelines for biomedical research on human subjects."[4] According to a report in the Bulletin of the World Health Organization, India has <40 IECs that are properly constituted and functioning.[5] This fact has been reiterated in many articles published in scientific journals.[6,7] Although guidelines pertaining to the structure and functioning of IECs were laid down on paper in 1980, they have not been implemented satisfactorily because they are not backed by the strength of legal protection. Thus, there are a number of problems associated with the functioning of IECs. Although in February 2013, the Government of India passed a rule making it compulsory for IECs to register themselves with the Central Drugs Standard Control Organization (CDSCO),[8] several challenges remain.

Since a large amount of research is carried out in various research institutions and hospitals under Baba Farid University of Health Sciences, Faridkot, hence to ensure the highest standards and compliance to Indian ethical guidelines, it is utmost important to understand and explore the quality and composition of the IEC which directly influence its performance. This could only be done by evaluating and assessing the key performance indicators for composition of the IEC, namely multidisciplinary nature, independent performance, competence, decision capability, professionally biased, and respect to the opinion of nonscientific members (ethicist, legal expert, and layperson). Till date, no such type of studies has been conducted in the health research institutes of Punjab. Therefore, a cross-sectional study was designed to collect information on the key performance indicators of the IEC.

MATERIALS AND METHODS

Study design

A cross-sectional study was designed in June 2015 and conducted over a period of 5 months (October to February 2015) after due approval from the Institutional Ethical Committee. The questionnaire was developed which consisted of questions related to general information; number of members in the IEC; and the questions aimed at obtaining the information such as existence of an IEC, its composition and main functions, approval of the Drug Controller General of India, and mechanisms for clearing ethical issues in research in case of absence of the IEC [Table 1]. This questionnaire was forwarded to 142 targeted institutions providing graduate/postgraduate

Table 1: Structured self-administered questionnaire

IECs questionnaire

Review of IEC structures and processes

1. Name of the institution
2. Whether your institution has an IEC, yes or no
   If no, please mention from where you approved your clinical research projects of faculty/research scholars/students (please indicate the name of the IEC along with its composition)
   If yes, please fill the following information:

General information

3. Mention numbers of years your institution is providing graduation/postgraduation education
4. Courses of graduation/postgraduation-medical/dental/nursing/physiotherapy/paramedical sciences/any other
5. Has your institution IEC been approved from the DCGI, New Delhi?
6. How long has this Institutional Ethics Committee been in operation?

Membership of IEC

7. How many members are in your IEC?
8. How many nonscientific members are in your IEC?
9. How frequently does the meeting of IEC take place in your institution?
10 Where is the office of your IEC?
11. Please indicate the detailed composition of the IEC of your institute
12. Please state the number of each of the following members, on the committee with their primary function/role is

Members	Number	Primary role
Medical doctor		
Scientist/researcher		
Psychologist		
Ethicist		
Layperson		
Nurse		
Statistician		
Legal professional		
Allied health professional		
Religious representative		
Please indicate any other member and its primary role		

IEC=Institutional Ethics Committee, DCGI=Drug Controller General of India

education in medical and health sciences which were under the jurisdiction of Baba Farid University of Health Sciences, Faridkot, Punjab (9 medical, 15 dental, 8 physiotherapy, 108 nursing, 1 paramedical sciences, and 1 sports medicine) and were requested to give their response by post/E-mail [Table 2]. A responsible person, for example, chief executive or principal from each of the respective institute was requested to complete the structured self-administered questionnaire.

Ethical consideration

The study plan was approved by the IEC of the University Institute of Paramedical Sciences, Baba Farid University of Health Sciences, Faridkot, Punjab, India.

Data analysis

The data received from the questionnaire were double-entered into the computer using Microsoft Excel with reconciliation done to develop a final master data file. Descriptive statistics was used to represent the data.

RESULTS

Response rate and existence of the Institutional Ethics Committee

Of the total 142 approached institutes, only 80 institutes responded to our request. The response rate was 56%. The institutes which responded were 5 medical colleges, 12 dental colleges, 5 physiotherapy colleges, and 58 nursing colleges. Sixty-five (81.25%) heath institutes had IEC, while in 15 (18.75%) health institutes IEC did not exist at all. The institutes were informed that failure in response will reflect no IEC in the institute. Despite that remaining 62 institutes did not respond to repeated requests. Only nine colleges (14%) had CDSCO registered ECs, while in remaining 56 colleges (86%) IEC was not approved by the CDSCO [Table 2].

Appointment of chairperson for the Institutional Ethics Committee

As per the schedule Y requirement, the chairperson of the IEC should be from outside the institution. In our study, authors found that 76% (50) institutes had a chairperson from inside the institute, i.e., head of the institution. Only 22% institutes complied with the schedule Y by keeping the chairpersons of the IEC from outside the institution [Table 2]. In our study, authors found that one institution had a layperson having postgraduation qualification appointed as chairperson for the IEC.

Multidisciplinary nature of the Institutional Ethics Committee

Only 35% health institutes have been found to have a multidisciplinary composition of the IEC. Only 53% committees had a legal expert, 47% had nonmedical scientists, 43% layperson, 35% ethicist, 33% religious representative, and allied health professional. The composition of members was not at all as per schedule Y [Table 3].

Biased nature of the Institutional Ethics Committee

The analysis of data depicts that the IEC of medical colleges/dental colleges comprised 3–8 doctors, whereas in nursing institutes, 1–13 number of nursing professionals was involved. This professionally biased nature could influence decision making. Only in 14 (22%) institutes, IECs have external members, while the remaining institutes IECs had only internal involved in the composition of the IEC.

Competence of the Institutional Ethics Committee

The IEC should comprise an adequate number of all members as per ICMR guidelines to function properly. Our data revealed the low percentage of a legal expert (53%), statistician (50%), scientist (47%), layperson (43%), ethicist (35%), religious representative (33%), and allied health professional (29%). Hence, in some institutes, there was no involvement of legal expert, layperson, and ethicist, which is important to preserve patient safety and rights.

DISCUSSION

Under schedule Y of the Drugs and Cosmetics Rules 1945, amended in 2005, in India, any agency conducting biomedical research using human subjects requires the approval of

Table 2: Details of institutes with Central Drugs Standard Control Organization-Registered Ethics Committees and schedule Y compliance

Total number of institutes	Institutes responded to the questionnaire (%)	Number of colleges having IEC (%)	Institutes with DCGI approval (%)	Institutes complying to schedule Y for chairperson (%)	Institutes not complying to schedule Y for chairperson (%)
Medical college (9)	5 (56)	5	3 (60)	5	0
Dental college (15)	12 (80)	12	2 (17)	5	7
Nursing college (108)	58 (54)	43	2 (3)	2	41
Physiotherapy college (8)	5 (63)	5	2 (40)	2	2
Paramedical (1)	0	0	0	0	0
Sports (1)	0	0	0	0	0
Total colleges (142)	80 (56 response rate)	65 (81.25)	9 (14)	14 (22)	50 (76)

IEC=Institutional Ethics Committee, DCGI=Drug Controller General of India

Table 3: Details of Institutional Ethics Committee member's specialty

Specialty of IEC members	Number of colleges (out of 65 institutes which possessed IEC)	Percentage
Medical doctor	52	80
Scientist	31	47
Ethicist	23	35
Layperson	28	43
Nurse	36	55
Statistician	33	50
Legal expert	35	53
Allied health professional	19	29
Religious representative	22	33
Others	7	11

IEC=Institutional Ethics Committee

its research protocol from an ethics committee before the commencement of a clinical trial/research study.[9] In our study, we found that average number of the members in the IECs of Punjab was ten (range 5–15 members). Some of the institutes took least efforts to constitute IEC and just had the minimum required members to meet the minimal requirement which is also seen in studies conducted earlier. Other challenges were the total absence of an IEC in the institute and inappropriate composition of IEC which hampered the smooth function of an IEC has been identified.[10]

Schedule Y of the Drugs and Cosmetics Act[11] mandates that the chairperson of an IEC should not belong to the same institution. As shown in results, 76% institutes had chairperson from inside the institute which results in loss of independence of IECs. Sometimes it influences on decision-making of the IECs, and unbiased decision could be taken that may be against the ethical principles. This could be essential to prevent institutionally biased nature so that decisions made are objective and independent of interest of investigator and institution.

The IECs should be multidisciplinary in composition and have at least one representative from the following groups: one chairperson, one or two persons from basic medical science area, one or two clinicians, one legal expert or retired judge, one social scientist/representative of nongovernmental voluntary agency, one philosopher/ethicist/theologian, one layperson from the community, and a member secretary.[9] The multidisciplinary foundation of the IEC rests on the collective expertise in the fields or disciplines deemed necessary for understanding that an ethics review must be guided by diverse viewpoints so that there should be an all-encompassing assessment of moral dilemmas that may arise before, during, and after a clinical trial/research studies. Multidisciplinary composition of an IEC is most desirable to adjudicate the research project properly. It must comprise active members who represent an appropriate balance of professional, ethical, legal, cultural, educational, and community interests. Our data revealed that the IEC of most of the research institutes lacked in multidisciplinary as shown elsewhere in the previous studies.[12]

As per standard guidelines, the appointment mechanism should ensure that potential IEC members provide an appropriate balance of scientific expertise, philosophical, legal or ethical backgrounds, and lay views making the IEC competent. The lawyer's role here may be as an expert in the relationship between law and ethics and as an advisor on the legal ramifications of the various options discussed. A legal expert can give suggestions that biomedical research using human subject is free from illegal harm and can take care of compensation issues related to clinical studies. The ethicist in an IEC keeps a check to control that the study participants are not enrolled unethically by including people from minority, a particular cast, race, or religion. Sometimes clinicians may not see things from a layperson's perspective, so a layperson can represent views as what kind of influence a research study can have to general public. Lay members of IECs are usually defined as having no specific qualification with respect to biomedical research, medicine, or health care, while in our cross-sectional study, it was found that one IEC included highly qualified persons as a layperson. In one qualitative study in the United States, a significant observation was that although there have been calls for increased representation of lay community members in IECs, little is known regarding their experiences or their perceptions of human subject protections and the IEC process.[13] However, in our study, there was a lack of legal representative, ethicist, layperson, and representative from the general community. It is important to ensure participation of IEC members in the field of social science, law, and community in a balanced proportion. Similar observations have also been made in one study carried out among IECs in the United States.[14]

All IEC members should have an equal standing irrespective of the scientific or nonscientific profession. Moreover, the involvement of nonscientific members should be encouraged. All members must endeavor to share the researcher's burden in seeking a balance between the pursuits of scientific interests on the one hand and the needs of society and the rights of research subjects on the other.[15] Some of the other issues that have been raised often are the inappropriate manner, inefficient, or professionally biased in the constitution of an IEC.[12,16-18] The IEC should be free from conflict of interest; however it has been observed that the composition of an IEC among health institutes is often influenced by the professional specialty of the college. The ethical review process must be free from institutional bias, but data showed that majority of members in the IEC of various institutes were professionally biased by including IEC members of their own institute specialties. Our data showed that in medical/

dental colleges, the number of the medical doctor or dentists (8–10 members) was more than the scientific and nonscientific members. Similar in nursing colleges up to ten IEC members were from the nursing profession. This creates an imbalance in the decisions taken out by the committee. There was lower involvement of nonscientific members (layperson, ethicist, and religious representative). It was observed that there were no legal experts on most of the IECs. Therefore, the IECs require selecting a chairperson who is unaffiliated to the institution so that decisions made are objective and independent of the interests of investigators and institutions.

CONCLUSION

A recent report from Clinical Trial Registry India revealed that there is a lack of awareness on regulatory processes, especially related to ethical review and many institutes have no IECs.[19] This study also revealed the total absence of IECs as well as many shortcomings in the constitution of IEC, professionally biased nature, and noncompliance with the schedule Y guideline. Moreover, the IECs are not well represented through lawyers, ethicists, and nonscientific members. There is a strong need to strengthen the contribution of nonscientific members in ethical evaluation of research proposals. The study reflects a lack of equal respect for all professionals in the IEC composition.

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Conflicts of interest

There are no conflicts of interest.

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