



## Original Article

# Institutional Ethics Committee (IEC) Awareness Index of The Project Leaders in Medical Research

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### ABSTRACT

**Introduction:** Ethics committee is supposed to play a great role in safe human research. It is mandatory that all research projects related to health sciences with involvement of patients/human subjects should be approved by IEC before commencement. Available data reflects low IEC awareness index amongst routine project investigators. Being inclined mainly towards teaching and research not being a mandatory part, IEC awareness index of faculty members is also not expected up to the mark. Indian Council of Medical Research has launched development of Multidisciplinary Research Unit (MRU) for igniting research component in medical colleges of India.

**Objectives:** A study was designed to check the awareness about the composition, review procedures and functioning of IEC collectively known as IEC awareness index amongst the project leaders in government medical colleges of Punjab.

**Methods:** Information was compiled in questionnaire from 50 participants who were either part of a research project or submitted a research project for funding.

**Results:** The study reflects that the average 32% participants were not aware about its composition and 86% felt need of extensive training before becoming a member of IEC. A stunning number of 14% participants were not at all aware about role of SOP in IEC review procedure. A few participants despite being member of IEC demonstrated a very poor IEC awareness index.

**Conclusions:** Data indicates need of serious efforts for training of faculty along with need to inculcate the IEC-ICH guideline in curriculum of post-graduate medical students.



## Introduction

The guidelines of the Indian Council of Medical Research (ICMR) state that biomedical research involving human participants requires mandatory approval from an appropriately constituted institutional ethics committee (IEC), also referred to as the institutional review board (IRB), ethics review board (ERB) and research ethics board (REB) in other countries. As mentioned in the Belmont report, the ethics committee (EC) must ensure beneficence, as well as justice and respect for research participants, thereby protecting their rights, safety and wellbeing<sup>1</sup>. This is also supported by the revised Schedule Y in Amendment 2005 of the Drugs and Cosmetics Act, 1940<sup>2</sup>, which is the local law.

The number of clinical trials in India has increased a great deal in recent years. The country is becoming a vulnerable hub of research for pharmaceutical companies due to the availability of a vast number of participants, a technically competent workforce, lower costs and a system of regulatory oversight that is relatively relaxed. Apart from this, due to the enormous progress in the field of research, multicentric studies, genetic studies, stem cell studies, etc, are increasingly being conducted in the country. A survey conducted by the ICMR in 2003 showed that only 200 of the more than 1200 institutions in India had functional IECs<sup>3</sup>. According to a report in the Bulletin of the World Health Organisation (WHO), India has less than 40 IECs that are properly constituted and functioning<sup>4</sup>. This fact has been reiterated in many articles published in scientific journals<sup>5</sup>.

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 connected with the functioning of IRBs. Even though in February 2013, the government of India passed a rule making it compulsory for IECs to register themselves with the Central Drugs Standard Control Organisation (CDSCO)<sup>6</sup>, several challenges remain. 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. Clinical research runs the potential risk of causing harm, and therefore sound standards of ethics must be established to protect research participants<sup>7</sup>. This has become more important in India where large numbers of clinical trials are being conducted and where such trials are likely to substantially increase in the coming years<sup>8</sup>.

Since a large amount of research is carried out in India by autonomous bodies as well as various research organizations and hospitals, it is necessary to understand and explore the quality and performance of ECs<sup>9</sup>. The performance of an ethics committee is expected to depend on its appropriate constitution and awareness of project coordinators as well as faculty members. In 2003, the ICMR with the World Health Organization conducted a survey on 223 institutional ethics committees in India<sup>10</sup> and found that many committees did not meet regulatory requirements in terms of composition and function. Since then, no reports have been published on this subject.

India is viewed as an ideal, cost-effective location for undertaking clinical trials, meeting international regulatory requirements<sup>11</sup>. However, institutional mechanisms for ethical review of research involving human participants in India are weak and vulnerable and a concerted effort is required to strengthen them to fulfill their stated missions<sup>12</sup>. Realizing the need for strengthening the ECs, the ICMR has been trying to promote the establishment of ECs

and has also started offering training programmes for EC members and researchers in ethics<sup>13</sup>.

Ethics committee is supposed to play a great role in safe human research<sup>14-20</sup>. It is mandatory that all research projects related to health sciences with involvement of patients/subjects should be approved by IEC before commencement. The pilot study data available reflects low percentage of awareness amongst the routine project investigators<sup>19</sup>. Being inclined much towards medical education, awareness amongst faculty members of medical colleges towards ethics committee is also expected not up to the mark. Only the faculty members involved in clinical trials or institutional research projects would be aware of the composition and functioning EC and that too in a compulsory manner (because of ethical committee clearance). Indian Council of Medical Research has launched and funded development of Multidisciplinary Research Unit (MRU), a scheme for igniting research component in various medical colleges of India. Keeping in view the above situation, present study has been aimed to assess the status, ethics training level and review procedures of institutional ethics committee of Medical and Health Sciences Institute of Punjab, India so as to make regulatory bodies like state health sciences universities and Central Drug Standard Control Organization (CDSCO), ICMR about true status and sanctity of IECs.

## Methodology

The study has been devised to know about the awareness level amongst faculty members that are the future principal investigators in projects to be funded under MRU from ICMR. A questionnaire was developed to evaluate important parameters of IEC awareness among faculty members actively involved in project writing and

already guiding MD/MS projects. The study was conducted in ICMR sponsored workshop on MRU Joint Project Development for faculty members and PG/PhD research scholars of Government Medical Colleges of Punjab. The study was so designed because the projects from medical colleges really need ethical clearance. The questionnaire was divided into two parts, first part had questions related to general information, constitution of IEC, training, activity levels, application process and review procedures of the IEC and second part of questionnaire had questions related to demographic data. The intention of compiling this information was to assess the real picture of IEC awareness amongst the principal investigators of different projects who are otherwise and ideally supposed to know everything about IEC.

The awareness about institutional ethics committee (IEC) was calculated by using awareness index. **IEC awareness index (I)** was calculated by formula  $A/B$  where 'A' is the number of wrong or unknown response given by the participants and 'B' is total number of participants in study. The values would range between 0.01 to 1.0, where the values approaching 1.0 correspond to the least acquainted area while the values near 0.01 corresponds to the most known or understood area of IEC.

IEC awareness index (I) =

$$\frac{A \text{ (number of wrong or unknown response)}}{B \text{ (total number of participants in study)}}$$

## Results and Discussion

The data obtained from questionnaire was compiled and results obtained have been explained as given below.

### 1. Importance of IEC

A basic question was designed to know about role of IEC, its mandate and

duty. The data compiled shows that 93% participants were aware of role and mandate of IEC. The subjects were also aware that research proposals need approval of IEC however there were still 7% participants who were not aware of IEC role, mandate and importance.

## 2. Composition

Information about constitution of IEC was compiled based on 7 questions highlighting about composition, chairperson, member secretary and representation of different categories of members. Average 68.5% participants were aware about the composition of IEC whereas 31.5% participants did not know about the composition of IEC. The subjects were also not aware about the mandate of composition (chairperson, member secretary, lay man, female member) of IEC. Data showed varied answer for the number of members in IEC only 6% respondents said member should not be more than five, 48% participants agreed that 6-8 members are sufficient in IEC constitution, 20% answered 8-12 and 8% respondents were agreed that members must be 12-16. However 18% participants were not aware about the number of members required for IEC constitution. This data highlight the point that more than half of the faculty members although involved in various research projects and having the contact with IEC were not sure about the number of members required for IEC constitution and only 20% respondents gave correct answer. Only 60% participants were aware about the fact that chairperson should be from outside the institution whereas 20% participants gave wrong answer and another 20% participants were not aware about the rule. Actually the importance of chairman from outside the institute highlights the importance of unbiased committee however the data shows the casual attitude of authorities constituting the ethical

committees. Similarly 74% participants were aware about the member secretary should be from inside the institution another 26% were not aware about this question. It is the part of basic information about the institutional ethics committee that must be known to the faculty of medical colleges. Only 60% respondents knew that the lay person should be from outside the institution, 18% gave wrong answer and 22% participants were not aware of this fact. In addition, 62% participants said that the female member is necessary for IEC, 24% participants including participants who serve as member of IEC said female member is not mandatory for IEC and 14% participants were not aware about the presence of female member in IEC. From all the participants a very less number (6%) of participants served as member of IEC. However from these 6% participants who served as member of IEC gave the most common wrong answer i.e. the chairperson of IEC should be from institution, and female member is not mandatory for IEC constitution.

## 3. Review proposal/steps

A set of six questions was made to assess the knowledge of participants about IEC Review proposal and procedure. A majority of participants (89.6%) were aware whereas only 10.4% participants were not aware about IEC review proposal and procedure. Data showed that 82% participants think that SOP is mandatory for IEC and only 4% participants thought that SOP is not necessary for IEC review procedures; however stunning 14% participants were not at all aware about role of SOP in IEC review procedure, however SOP is necessary for IEC review procedure so that the work is done in compliance with ICH-GCP guidelines or with the ethical guidelines of ICMR.

#### 4. Served as member of IEC

There was one question to know whether the participants ever served as member of IEC. Authors were intended to know about the knowledge index of the subjects who were served as members of IEC or at present were members of IEC. Data showed that only 6% participants served as member of IEC and these members were even not aware about the composition of IEC for example they were not aware that the chairperson should be from outside the institution. However other 94% participants never served as member of any IEC.

#### 5. Training necessity

The basic question of whether or not there is a need of training to IEC members about IEC regulations, widely differing responses from the medical profession. The fact that the majority of respondents (86%) felt that there was a need for some 'training' before becoming a member of IEC and another 14% respondents felt that the training is not mandatory for IEC members.

#### 6. Training level

There was one question to assess the information about how many participants undergone the training of IEC (ICH-GCP). Data showed that only 10% participants undergone the training another 90% participants had not undergone any training of IEC. Results of survey demonstrate that very less number of participants (faculty of medical colleges) undergone the training about IEC (ICH-GCP) which is very necessary for the faculty of health institutions. Some members did not have knowledge of the functioning of IECs that leads to conclusion that there is the absence IEC training (ICH-GCP). Faculty of a medical college should be trained about ICH-GCP (Table 1).

The overall scores of the study about the knowledge and functioning of the IEC were listed in Table 2.

#### IEC Awareness Index

The prefabricated twenty questions were also evaluated with awareness index tool. The questions which had values approaching  $\leq 1$  were the areas where majority of the participants were unaware about the IEC. These areas were regarding the number of IEC members, their involvement as IEC member and their training for ICH-GCP. On the other hand, the participants were well aware about the IEC basics, composition, area under IEC review and processes as depicted by the index score of  $\leq 0.01$ . Hence, on the basis of the index values, it is clear that the participants had some knowledge and were not naïve to IEC (Table 3). However, they require acquaintance on the technical requirement for IEC, lack experience of having formal training on IEC which could have resulted them not being a member of IEC.

#### Conclusions

From the data it is very clear that there is strong need of training to faculty of medical colleges towards institutional ethical committee. There is a need to inculcate the IEC-ICH guideline in curriculum of graduates/postgraduates in medicine and health sciences so as to enable university to impart basic knowledge as a mandate. There is a great need to consider a component of seriousness and responsibility towards selecting members of ethical committee with stipulated composition. This will definitely help regulatory authorities like Central Drugs Standard Control Organisation (CDSCO) in regulating unethical human use in clinical trials and research studies thus providing better services to mankind.



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## Conflict of Interest

Nil

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**Table 1.** Awareness index amongst project investigators about Institutional Ethics Committee

S. No.	IEC parameter	% age
1.	Importance	93.0
2.	Composition	68.5
3.	Review proposal/ Review procedure	89.6
4.	Served as member of IEC	6.0
5.	Training necessity	86.0
6.	Training level	10.0

**Table 2.** Questions in questionnaire for participants

S. No.	Institutional Ethics Committee Parameter	Yes/Correct answer (%age)	No/Wrong answer (%age)
1.	IEC stands for	49(98)	1(2)
2.	Role of IEC	43(86)	7(14)
3.	Ideal number of members in IEC	10(20)	40(80)
4.	Members of IEC	49(98)	1(2)
5.	IEC is mandatory for every health institute	47(94)	3(6)
6.	Have served as chairman/member secretary/member of IEC	3(6)	47(94)
7.	Chairman of IEC should be from	30(60)	20(40)
8.	Can a head of institute become chairperson of IEC in same institute	30(60)	20(40)
9.	Member secretary of IEC	37(74)	13(26)
10.	Lay person associated	30(60)	20(40)
11.	Is female member necessary in IEC or not	31(62)	19(38)
12.	Is it necessary to obtain IEC approval before a non-sponsored research project is started?	45(90)	5(10)
13.	Does IEC review procedures require a standard application form?	41(82)	9(18)
14.	IEC review research proposals for	45(90)	5(10)
15.	IEC review research proposals	48(96)	2(4)
16.	Steps in IEC review	41(82)	9(18)
17.	If an application is refused, does the IEC provide an opportunity to re-appeal?	46(92)	4(8)
18.	Is the record keeping compulsory for IEC meetings?	48(96)	2(4)
19.	Have you undergone training for ICH-GCP?	5(10)	45(90)
20.	Do you think that training / orientation to IEC members?	43(86)	7(14)

**Table 3.** IEC Awareness Index

S. No.	Institutional Ethics Committee Parameter	%age
1.	Knowledge about IEC	<b>0.02</b>
2.	Role of IEC	<b>0.14</b>
3.	Ideal number of members in IEC	<b>0.8</b>
4.	Members of IEC	<b>0.06</b>
5.	IEC is mandatory for every health institute	<b>0.06</b>
6.	Have served as chairman/member secretary/member of IEC	<b>0.94</b>
7.	Chairman of IEC should be from	<b>0.4</b>
8.	Can a head of institute become chairperson of IEC in same institute	<b>0.4</b>
9.	Member secretary of IEC	<b>0.26</b>
10.	Lay person associated	<b>0.38</b>
11.	Is female member necessary in IEC or not	<b>0.38</b>
12.	Is it necessary to obtain IEC approval before a non-sponsored research project is started?	<b>0.1</b>
13.	Does an IEC review procedure require a standard application form?	<b>0.28</b>
14.	IEC review research proposals for	<b>0.1</b>
15.	IEC review research proposals	<b>0.04</b>
16.	Steps in IEC review	<b>0.18</b>
17.	If an application is refused, does the IEC provide an opportunity to re-appeal?	<b>0.08</b>
18.	Is the record keeping compulsory for IEC meetings?	<b>0.04</b>
19.	Have you undergone training for ICH-GCP?	<b>0.9</b>
20.	Do you think that training / orientation to IEC members?	<b>0.14</b>