

# Awareness among Teaching Faculty about Ethics Committees in a Medical College of Kolkata: An Observational Study

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## ABSTRACT

**Background:** An observational cross sectional study was performed to assess the overall knowledge of the respondent about both clinical and animal research ethics committees. **Objective:** To study the perceptions amongst the medical teaching faculty regarding types, composition, roles and responsibilities of both institutional clinical and animal research ethics committees. **Methods:** After prior approval from the Institutional Ethics Committee (IEC), a standardized audit-based pre-validated close-ended questionnaire was supplied to the willing faculty within the Medical College premises, who instantaneously filled-up the questionnaire and returned it to the investigator. The questionnaire consisted of 20 close-ended questions, 10 each regarding animal and clinical research ECs. The results were statistically analyzed to assess the awareness and knowledge of medical teaching faculty about institutional ethics committees. **Results:** 87 faculty were approached of whom, 70 consented to participate. Out of a total of 20 questions, mean of questions answered correctly was  $11.87 \pm 2.32$  (Mean and Standard deviation). When the faculty were grouped as per their designation, the mean scores were ( $11.33 \pm 2.33$ ) for the Assistant Professors, ( $12.86 \pm 2.41$ ) for the Associate Professors, ( $11.0 \pm 02.6$ ) for Professors, ( $13.17 \pm 1.94$ ) for Senior residents and ( $12.35 \pm 2$ ) for Tutors. The difference between the groups were not statistically significant. **Conclusion:** The overall quality of knowledge and awareness regarding details pertaining to the structure and functioning of IECs were sub-par when compared to results of similar studies done elsewhere.

**Keywords:** Ethics committee, teaching, faculty, awareness, medical college.

## INTRODUCTION

In India, Ethics Committees (ECs) are established in different medical institutions to protect the rights, safety and confidentiality of the participating subjects in a research study. It has now been made mandatory legally that all research protocols in India, involving human subjects or studies involving experimental animals receive prior approval from registered institutional or independent ethics committees before undertaking the study.

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During the course of the study, the researcher is supposed to update the concerned ECs with all

necessary information arising from the study. The purpose, composition and responsibilities of clinical research ECs are different from that of animal ECs. The former is guided mostly by Schedule Y whereas the later is guided as per the Prevention of Cruelty to Animals (PCA) Act and Schedule Y, under supervision by the Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA), the acts being amended from time to time as per situations demand.

Though research involving human subjects as well as experimental animals are an integral part of the Indian medical curriculum in undergraduate and postgraduate education, to what extent faculty are actually involved in formal training of students regarding ethical principles, research ethics and ethics committees - is grossly unexplored.<sup>[1]</sup> Despite a diligent literature search, a very few previous Indian studies were found reflecting knowledge and perceptions of teaching faculty regarding functioning of ECs.<sup>[2]</sup> In those studies, considerable fraction of the faculty members were found to have a dearth of

relevant knowledge regarding ECs. Only few persons who were actively involved in conduct of clinical trials or institutional research projects were well informed.

To the best of our knowledge, there has been no published study reflecting awareness of medical teachers about ethics committees in the eastern part of India. This study was designed to be conducted in a Government-run Medical College and Hospital in Kolkata to assess the awareness of medical teaching faculty regarding a few important aspects of clinical research ethics committees and animal ethics committees.

### **Aim and Objectives**

The study site which is a Government-run Medical College and Hospital, consists its own Clinical research EC as well as an Animal Ethics Committee, both being fully functional. This study was planned to assess the knowledge regarding the

existence, composition, responsibilities and functioning of the institutional clinical research EC and institutional animal EC, amongst the undergraduate and postgraduate medical teachers who had been associated with the medical college or hospital at least since the past six months.

## **MATERIALS AND METHODS**

Accordingly, a questionnaire-based observational cross sectional study commenced after due approval from the institutional Clinical Research EC. A pre-tested and pre-validated questionnaire consisting of 20 close-ended dichotomous questions was used [Table 1]. The questions consisted of knowledge about the composition of both institutional clinical research and animal ECs and their functioning, in general.

**Table 1: Questionnaire to assess awareness among the faculty about Ethics committees.**

<ul style="list-style-type: none"> <li>✓ Time allotted: 10 minutes</li> <li>✓ Please answer and return the questionnaire immediately</li> <li>✓ Please answer in exact order, avoiding over-writing</li> <li>✓ Answers once answered cannot be changed later</li> <li>✓ Please answer without any assistance</li> </ul>			
<b>Particulars of the Study Participant</b>			
<b>Name (optional):</b>		<b>Age:</b>	
<b>Department:</b>		<b>Designation:</b>	
<b>No of Years in this institution:</b>		<b>Total Teaching experience: _____ years PG Teacher: Yes / No Past experience as PG Teacher: Yes / No</b>	
<b>Experience as Member of Institutional Ethics Committee: Yes / No</b>			
<b>Questionnaire (to be filled by the participant)</b>			
	<b>Yes</b>	<b>No</b>	<b>Don't know</b>
1. Research projects in our institution are reviewed by Independent (non-institutional) Ethics Committees.			
2. Ideally, a clinical ethics committee should have 12-16 members as per ICMR guidelines.			
3. A minimum of three non-scientific members are required to be present in a meeting of the clinical research ethics committee, to form a quorum.			
4. In the clinical ethics committee, eight members are required to form a quorum while conducting a meeting.			
5. Dean is the chairperson of our institutional clinical ethics committee.			
6. Member Secretary of an institutional clinical ethics committee in a medical college should be a faculty of the institution.			
7. Is it necessary to take permission from ethics committee before starting a non-interventional study and/or observational study?			
8. It is mandatory to include scientific member/s from outside the institution while constituting the institutional ethics committee.			
9. A clinical ethics committee should ensure that in a new drug trial, audio-visual recording of informed consent procedure on trial participants is mandatorily performed.			
10. Legal expert is mandatory for any clinical research ethics committee.			
11. Clinical ethics committee plays a major role in taking decisions regarding compensation issues owing to adverse events during a clinical drug trial.			
12. Institutional animal ethics committee should be separate from institutional clinical ethics committee			
13. All animal ethics committee members are selected by the institution.			
14. Veterinary surgeon is an essential person in the animal ethics committee.			
15. Ideally, an animal ethics committee should have 7 members as per CPCSEA guidelines			
16. Dean is the chairperson of our animal ethics committee.			
17. In the animal ethics committee, it is absolutely necessary to include scientific member from outside the institution.			
18. A minimum of two non-scientific members are required in an animal ethics committee.			
19. A researcher has the right to continue his/her project without prior approval from clinical or animal ethics committee.			
20. Ethics committees are to be mandatorily constituted in every Medical College.			
<b>Total number of correct responses:</b>			

The questionnaire form was supplied to the institutional faculty including Professors, Associate Professors, Assistant Professors, Senior Residents and Tutors belonging to different medical disciplines who had duly consented to participate in the study by signing the informed consent form. Data were collected only from Medical Faculty within the premises of ESI, PGIMSR, ESIC Medical College, Joka. Only those who were assigned with teaching designations for at least 6 months were included. All Faculty members of the department of Pharmacology, ESI PGIMSR and ESIC Medical College Joka were excluded as some of them were contributing to the design and conduct of this study. The respondents were required to fill in the questionnaire in front of the investigator or the designated person, and return it immediately. A maximum time of ten minutes was allotted for the participants to complete the questionnaire and he/she was not allowed to converse during the procedure. Questionnaire forms which were not filled and returned immediately were rejected from the analysis. Confidentiality and privacy of the respondents were strictly maintained throughout the procedure. 70 faculty members from different

medical disciplines participated in this study for 1 month.

Among a total of 20 questions, each correct response was given a score of 'one'. The summation of correct responses to the questions were scored numerically against a total score of 20. Numerical parameters so obtained were entered and analyzed using SPSS (version 20). Between group comparisons was done in addition to descriptive statistical analysis.

## RESULTS

The data was analyzed by using SPSS (version 20) software. 70 faculty out of 87 consented to participate in the study. Awareness of faculty members regarding clinical and animal ethics committees were estimated by analyzing the questionnaire [Table 1]. Mean correct score to responses given by all participants was  $11.87 \pm 2.32$  (Mean and Standard deviation) out of a total score of 20. When grouped according to their designations, mean scores were  $11.33 \pm 2.33$  for Assistant Professors (Group 1),  $12.86 \pm 2.41$  for Associate Professors (Group 2),  $11.00 \pm 2.6$  for Professors (Group 3),  $13.17 \pm 1.94$  for Senior residents (Group 4) and  $12.35 \pm 2$  for Tutors (Group 5).

**Table 2: Percentage of Correct Responses to Individual Questions.**

Questions	Total Number of Responses	Number of Correct Responses	Percentage of Participants Answering Correctly
1. Research projects in our institution are reviewed by Independent (non-institutional) Ethics Committees.	70	15	21.43 %
2. Ideally, a clinical ethics committee should have 12-16 members as per ICMR guidelines.	70	15	21.43 %
3. A minimum of three non-scientific members are required to be present in a meeting of the clinical research ethics committee, to form a quorum.	70	51	72.86 %
4. In the clinical ethics committee, eight members are required to form a quorum while conducting a meeting.	70	40	57.14 %
5. Dean is the chairperson of our institutional clinical ethics committee.	70	22	31.43 %
6. Member Secretary of an institutional clinical ethics committee in a medical college should be a faculty of the institution.	70	50	71.43 %
7. Is it necessary to take permission from ethics committee before starting a non-interventional study and/or observational study.	70	59	84.29 %
8. It is mandatory to include scientific member/s from outside the institution while constituting the institutional ethics committee.	70	51	72.86 %
9. A clinical ethics committee should ensure that in a new drug trial, audio-visual recording of informed consent procedure on trial participants is mandatorily performed.	70	51	72.86 %
10. Legal expert is mandatory for any clinical research ethics committee.	70	17	24.29 %
11. Clinical ethics committee plays a major role in taking decisions regarding compensation issues owing to adverse events during a clinical drug trial.	70	46	65.71 %
12. Institutional animal ethics committee should be separate from institutional clinical ethics committee	70	50	71.43 %
13. All animal ethics committee members are selected by the institution.	70	41	58.57 %
14. Veterinary surgeon is an essential person in the animal ethics committee.	70	57	81.43 %
15. Ideally, an animal ethics committee should have 7 members as per CPCSEA guidelines	70	37	52.86 %
16. Dean is the chairperson of our animal ethics committee.	70	33	47.14 %
17. In the animal ethics committee, it is absolutely necessary to include scientific member from outside the institution.	70	50	71.43 %
18. A minimum of two non-scientific members are required in an animal ethics committee.	70	23	32.86 %
19. A researcher has the right to continue his/her project without prior approval from clinical or animal ethics committee.	70	61	87.14 %
20. Ethics committees are to be mandatorily constituted in every Medical College.	70	62	88.57 %

On between group comparisons, the difference between the groups were not statistically significant ( $p = 0.127$ ).

When percentage of correct responses to each question was analyzed [Table 2], question number 20 (regarding whether Ethics committees are to be mandatorily constituted in every Medical College) was correctly answered by most (88.57%) of the faculty. The first two questions (regarding review process of research projects in our institution and constitution of clinical research ethics committee, respectively) were incorrectly answered by most. Only 21.43% of faculty answered each of them correctly.

When analyzed based on the duration of teaching experience, mean score of teaching faculty who have been in this profession for more than 5 years was 11.41 (with an SD of 2.67), whereas that for faculty working less than 5 years was 12.03 (SD of 2.04), with no significant difference between the two groups ( $p = 0.289$ ). Also, no significant difference in the knowledge scores of participants who were post-graduate medical teachers, as compared to undergraduate medical teachers, though the numbers of post-graduate teachers in our institution were very few in number.

A considerably large portion of the participants (68.43%) wrongly considered the Dean of our institution as chairperson of clinical ethics committee.

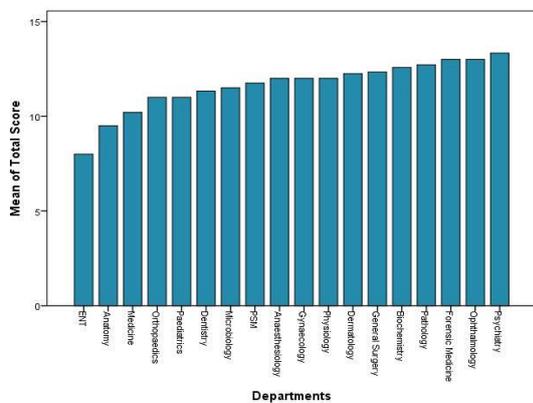


Figure 1: Mean of total score in different departments.

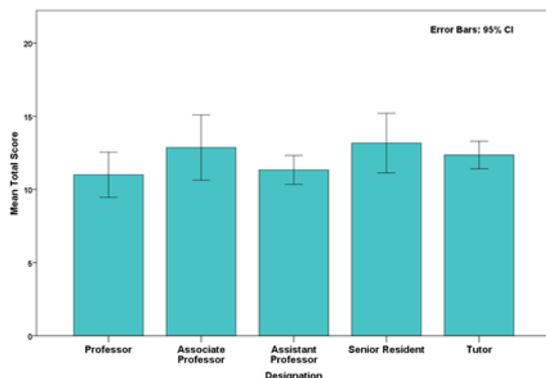
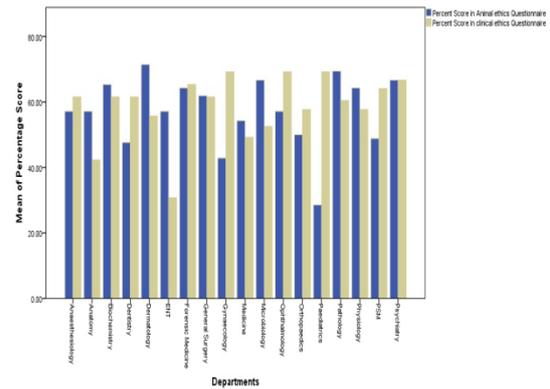


Figure 2: Mean total score according to designation.



institution as chairperson of clinical ethics committee.

Though no other similar studies were found among medical teachers, a few studies have been found to assess the awareness among medical and para-medical students. In a descriptive, cross-sectional study conducted to assess the knowledge of and attitudes towards medical ethics among undergraduate medical students in West Bengal<sup>[3]</sup>, 340 medical students of a medical college in West Bengal were given a semi-structured questionnaire that included questions regarding their awareness of ethics, their attitudes towards various issues in clinical ethics, and their knowledge of the code of medical ethics. Only 10.9 % were aware of the existence of an institutional ethics committee and 42.8% did not know its exact role. No increase in relevant knowledge was found among those with additional years of medical education.

A cross-sectional questionnaire-based study among final year undergraduates of paramedical sciences in a teaching hospital in Coimbatore assessed how respondents felt about the need for ethical approval before the start of the study and other aspects of clinical research, including participant's autonomy, monitoring of study, studies requiring ethical clearance, members of ethical committee and roles of ethics committee.<sup>[4]</sup> Among a total of 161 paramedical undergraduate participants, a statistically significant difference was found between researchers and non-researchers regarding awareness about ethics committees. This study emphasised the need for introducing medical ethics in course curriculum and conducting period workshops or seminars to increase their awareness on ethical approval process in research.

In another study done in the Middle East on dental faculty the researchers found that many of the respondents might not understand the extent of the processes needed for an adequate review of research.,<sup>[5]</sup> Less than a third of all of the respondents stated their familiarity with the functions of ECs, highlighting the need for efforts to enhance faculty awareness about the operations of the ECs.

Unawareness and lack of knowledge regarding ethics committees and about research ethics, in general, lead to consequences such as faulty and unethical research practices. In a meta-analysis of surveys done to estimate the frequency with which scientists fabricate and falsify data, a pooled weighted average of 1.97% (N=7, 95% CI: 0.86–4.45) of scientists admitted to have fabricated, falsified or modified data or results at least once and up to 33.7% admitted other questionable research practices. In surveys asking about the behaviour of colleagues, admission rates were 14.12% (N=12, 95% CI: 9.91–19.72) for falsification, and up to 72% for other questionable research practices.<sup>[6]</sup>

There have been several limitations to our study. Firstly, since our study was based on convenience sampling, professionals reluctant about clinical research may have opted out of the survey, thus the findings may not have reflected the awareness and knowledge of the faculty of the entire institution. Secondly, attitude and practice of participants could not be simultaneously assessed due to logistic constraints. Thirdly, since the total number faculty in our institutional is relatively less, the sample size for this study could not be increased further. Lastly, time constraints prevented us from designing a prospective study where in addition to the present study, we could have assessed the effects of subtle interventions to increase awareness regarding ethics committees and ethical issues in clinical research.

Studies like this emphasize the need to develop methods to create awareness among faculty members to promote quality research. Measures such as regular workshops on Bioethics or distributing relevant educational materials about the roles and responsibility of research ethics committees to the institutional teaching faculty have been suggested, but to what extent these are actually beneficial, need to be further investigated. We contemplate to explore different ways to enhance awareness among faculty of our institution, through future research studies.

## CONCLUSION

The overall quality of knowledge and awareness among teaching faculty regarding details pertaining to the structure and functioning of IECs were sub-par when compared to results of similar studies done elsewhere.

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