

Original Research Article

Attitude of researchers towards ethics committee at a medical research institute in Coimbatore: a cross sectional study

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ABSTRACT

Background: The role of ethics committees has been well defined, but many researchers regard ethical review as a road block to research.

Methods: To assess the attitude of the researchers towards the ethics committee, a cross sectional study was conducted among 80 researchers, which includes both faculty and undergraduate students at a medical research institute.

Results: Our study shows that though most of the researchers agreed that ethics committee is mandatory, they felt that ethics committee review delays research projects, undermined the role of non-medical members in the committee, felt annoyed about the documentation and answering the full board queries and presentations.

Conclusions: Study concludes that though the researchers have understood the critical role of ethics committee, they lack a positive attitude when it comes to the ethics committee functioning. Therefore, training should be conducted for researchers, which addresses these issues, so that the misunderstandings and conflicts are minimized.

Keywords: Academics and institutes, Attitude, Ethics committee, Research personnel

INTRODUCTION

WHO has defined ethics committee as a group of individuals who undertake the ethical review of research protocols involving humans, applying agreed ethical principles.¹

The Helsinki declaration made a clear description of the role of ethics committee in research. It highlighted the transparency and independency of ethics committee. The committee was also to function according to the local laws and regulations. In addition, it confers the right of monitoring of research and also serious adverse events during the conduct of research. Any changes or amendments made to the submitted and approved

protocol has to be communicated to the ethics committee and the researcher must also submit a final report containing a summary of the study findings and conclusions.²

Though the roles of the ethics committee has been clearly defined by guidelines and regulations, it should be noted that many researchers regard ethics committee review as a road block to research, and slowing the progress of scientific research.³ There is always some difference of opinion between the Ethics committee members and Researchers which gives rise to misunderstanding or conflict. One of the roles of Ethics committee is to advise researchers on how to improve their scientific methods and ensure that a study is conducted scientifically sound.

This is the major area of discrepancy between Ethics committee and researchers. This may be attributed to the lack of knowledge of researchers about institutional review committees, the ethical review process, and elements of ethical review, research regulatory guidelines and laws.⁴ Some studies have also discussed about the paternalistic attitude of the ethics committee.⁵

Though lot of studies has assessed the attitudes of researchers towards research ethics, not many have assessed the attitude towards the ethics committee, which largely influences the practices of research ethics among these researchers. Hence the study was conducted to assess the attitude of researchers towards research ethics committee and its role in conducting a research in a research institute.

METHODS

The study was approved by our Institution Human Ethics Committee. A cross sectional study was conducted among researchers in a medical research institute, to assess their attitude towards the ethics committee. Study population included doctors and undergraduate MBBS students who were involved in research and the study period was from September 2018 to November 2018. Those participants who had experience of submitting proposal to ethics committee at least once and willing to participate were included in the study and those not involved in research and have not submitted research proposal to ethics committee were excluded from the study.

Sample size calculation

Based on the previous study which states that 97% believe that ethics committees are either average or really good and taking 5% precision and 20% non-response the sample size was calculated to be around 65.⁶

Informed consent was obtained from the participants and data was collected using a questionnaire which assessed the attitude of the researchers towards the ethics committee. The questionnaire had two parts. One part had general questions such as age, gender, designation, years of experience, number of publications and training workshops undergone. The second part had 16 items describing the roles of ethics committee, need for ethics review, members of ethics committee and documentation process required by ethics committee. The questionnaire was validated by face validation with a group of experts trained in research ethics. The participants rated their response on a Likert scale ranging from 1-5 (“strongly agree”=1, “agree”=2, “neutral”=3, “disagree”=4, “strongly disagree”=5). For analysis purpose 1 and 2 were considered as agree and 4 and 5 were considered as disagree.

Survey was made anonymous by not collecting the name of participants. A total of 80 participants completed our survey and they were chosen by convenience sampling. Data was entered in excel and statistical analysis were done using SPSS Version 24. The descriptive data are given in percentage. The association of the variables with the attitude were done using t-test.

RESULTS

A total of 80 participants were included in the study among which 50 (62.5%) were undergraduate students and 30 (37.5%) were doctors. Among the doctors, 4 (5%) were senior residents, 7 (8.8%) were assistant professors, 12 (15%) were associate professors, 7 (8.8%) were professors. 54 (67.5%) were males and 26 (32.5%) were females.

Among the participants 69 (86.3%) had undergone at least one training in research ethics and 36 (45%) had one or more publications.

Table 1: Attitudes of researchers towards ethics committee.

Attitude towards ethics committee	Agree	Neutral	Disagree
	N (%)	N (%)	N (%)
I feel ethics committee should review ethical issues only	42 (52.5)	18 (22.5)	20 (25)
I feel ethics committee should review Scientific issues only	18 (22.5)	22 (27.5)	40 (50)
I feel the role of ethics committee is mandatory in a research institute	74 (92.5)	5 (6.2)	1 (1.3)
I feel medical research projects require an ethical committee review	72 (90)	5 (6.2)	3 (3.8)
I feel only well accomplished researchers should be reviewers in an ethical committee	52 (65)	13 (16.2)	15 (18.8)
I feel certain aspects of research design needs more ethical attention than any others	53 (66.2)	20 (25)	7 (8.8)
I feel non-medical members have a significant role in an ethical committee	38 (47.5)	32 (40)	10 (12.5)
I feel a system for monitoring progress in research should be adopted	66 (82.5)	8 (10)	6 (7.5)
I feel ethics committee review delays the research projects	30 (37.5)	23 (28.7)	27 (33.8)
I feel ethics committee should restrict its' involvement for high risk research only	24 (30)	18 (22.5)	38 (47.5)
I feel submission to and clearance from ethics committee is an additional burden for researches of minimal risk category	35 (43.8)	16 (20)	29 (36.2)

Continued.

Attitude towards ethics committee	Agree	Neutral	Disagree
I feel ethics committee is an hindrance to any research project	7 (8.8)	15 (18.6)	58 (72.6)
I feel it is time consuming when ethics committee calls for presentation to full board	23 (28.7)	27 (33.8)	30 (37.5)
I feel documentation required for protocol submission is extensive	42 (52.5)	17 (21.2)	21 (28.3)
I feel annoyed when ethics committee asks queries in my protocol submission	27 (33.8)	20 (25)	33 (41.2)
I feel the submission of closure reports for research projects is unnecessary	13 (16.3)	23 (28.7)	44 (55)

The attitudes of researchers towards ethics committee were assessed using the questionnaire and the results are tabulated in (Table 1).

Table 2: Association of variables with the attitude score.

Variable	Group	Mean±SD	P value
Gender	Male	7.9±3.9	0.608
	Female	7.5±3.6	
Publications	Yes	9.3±3.9	<0.001
	No	6.2±2.9	
Training	Yes	7.6±3.7	0.808
	No	7.9±3.7	
Designation	Faculty	9.8±3.9	<0.001
	Students	6.3±2.9	

The association between mean score of attitude and gender, publications, research ethics training and designation were analyzed and the findings are expressed in (Table 2).

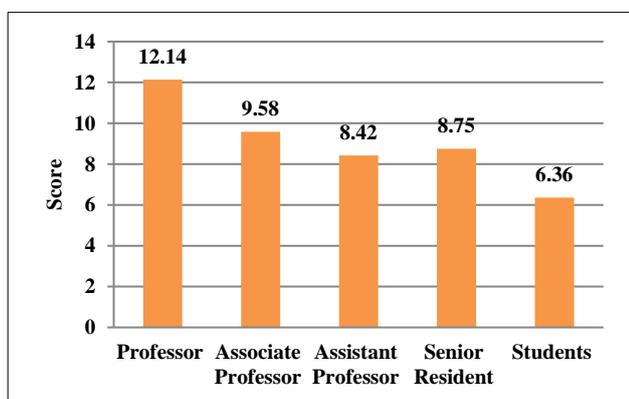


Figure 1: Attitude score based on designation of participants.

It was found that the mean attitude score had moderate positive correlation with age of participants ($r=0.50$, $p<0.001$), number of years of experience in research ($r=0.42$, $p=0.022$) and number of publications ($r=0.42$, $p<0.001$).

The mean score was also compared with the designation of participants and the same is expressed in (Figure 1).

The difference was found to be statistically significant ($p<0.001$).

DISCUSSION

In our study 92.5% of participants agree that the role of ethics committee is mandatory in a research institute and 90% feel that medical research projects require ethical review. Nearly 72% disagree that ethics committee is a hindrance to any research project. This showed that participants had a positive attitude towards the need for the ethics committee and its importance in reviewing research projects. This may be attributed to the increasing trend towards medical research involving human subjects as a part of increasing the standards of health care and the pressure for publications by medical faculty for promotion and academic needs. This has been evident in few studies in Sudan and Egypt and also an Indian study by Mallela et al which reported that 96.2% of respondents had accurate knowledge about ethics committee.⁷⁻⁹

However, 52.5% of researchers feel that the committee has to review ethical issues only and 66.2% feel that certain aspects of research design needs more ethical attention than any others. But the ICMR guidelines 2017 clearly states that the Ethics committee should review all scientific, ethical, medical and social aspects of research proposals received by it and must ensure that universal ethical values and international scientific standards are followed in terms of local community values and customs.¹⁰

Regarding the members of ethics committee, 65% researchers feel that only well accomplished researchers should be reviewers in an ethics committee and 47.5% felt that non-medical members have a significant role in an ethical committee. The recent ICMR guidelines have clearly stated the list of members in ethics committee and their roles. It shows the role of each member and how non-medical persons in the committee have a significant role to play. It also mandates that they are required to undergo initial and continuous training in human research protection and related regulatory requirement.

A total 47.5% disagree that ethics committee should restrict its' involvement for high risk research only. However, 30% agree to the same and 43.8% of participants agree that ethics committee review process is an additional burden for research involving minimal risk.

International Committee of Medical Journal Editors and Committee on Publication Ethics guidance has recently been updated and suggest that any research involving humans should be subject to prior ethical review.^{11,12}

Certain types of projects such as quality-improvement projects, audits, research on anonymous or non-identified data/samples, data available in public domain involve less than minimal risk to participants. Though there are arguments questioning the need for ethical review in these conditions, it is mandated by ICMR guidelines that it may be subjected to exempt review by the ethical committee.

In our study 37.5% feel ethics committee review delays the research projects and 52.5% feel documentation required for protocol submission is extensive. Our findings were consistent with the study by Saddam et al which stated 37% participants believed that review of research by Ethics Committee would delay research and make it harder.¹³

Attitude of researchers about presenting in full board review meeting as time consuming (28.7% agree, 33.8% gave no opinion and 37.5% disagreed) and feeling annoyed about responding to queries by ethics committee to research protocols (33.8% agree, 25% gave no opinion and 41.2% disagreed) had inconclusive differing opinions.

The study also showed that age of the researchers, years of experience and number of publications all had a moderate correlation with attitude of the researchers; with more experience and number of publications the attitude was more positive and better towards the committee. This might be because more they encounter with the committee, better they have understood how things are done and that could have led to better attitude score. Also based on designation the senior faculties like professors and associates had better attitude than senior residents or assistant professors. Again, this might be because the younger faculties are new to research and have less experience while the researchers who are experienced had better attitude towards research. The same was reflected between students and faculties. Faculties had a better attitude than students which was found to be statistically significant.

Our study also showed that training did not play a significant role in influencing the attitude towards the ethics committee. This might be because training usually addresses the ethics issues in research and how researchers should protect their participants from harm due to research. It had failed to address how actually an ethics committee work to take care of the ethical issues in their research proposals and how it plays a role in improving their research both scientifically and ethically. The same was also emphasised in a study done in Kampala, that recommended that the researchers should

be continuously educated about all functions of the ethics committees, and the review process.⁴

Limitations of this study was conducted in a single institute so extrapolations of the findings are questionable.

CONCLUSION

Our study shows that though most of the researchers agreed that ethics committee is mandatory, they felt that ethics committee review delays research projects, undermined the role of non-medical members in the committee, annoyed about the documentation and answering the full board queries and presentations. Thus, we would conclude that though the researchers have understood the critical role of ethics committee, they lack a positive attitude when it comes to the ethics committee functioning. This might be because researchers do not have much knowledge about the functioning of the committee. Therefore, training should be conducted for researchers, which addresses the roles and responsibilities of ethics committee and its members and how review process takes place in the committee, so that the misunderstandings and conflicts are minimized. This is an important aspect in training as understanding makes the researchers more compliant to the review committee protocols thereby ensuring research ethics and participant protection.

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