**Title:**

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

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**Abstract**

The role of Ethics Committees has been well defined, but many researchers regard ethical review as a road block to research. Hence 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. 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. 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:** Ethics committee, attitude, research personnel, academics and institutes.

**Main article**

**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]

Declaration of Helsinki has clarified the role of research ethics committee stating that the committee must be transparent and independent. It also stated that consideration should be given to the laws and regulations of the country in which the research is done. Also the committee must have the right to monitor research and the researcher must provide information about the research, especially information about any serious adverse events. No amendment to the protocol may be made without consideration and approval by the committee. At the end of the study, the researchers must submit a final report to the committee 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 ethical review as a road block to doing research, and slowing the progress of science, imposed by institutional review committees.[3]There always exists a difference of opinion between the Ethics committee members and Researchers which continues to be a source of 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 minimal knowledge of the 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.

**Methodology**

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. 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% [6] 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.

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&2 were considered as agree and 4&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.

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

**Table 1: Attitudes of researchers towards ethics committee**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **S.No.** | **Attitude towards ethics committee** | **Agree (%)** | **Neutral** | **Disagree (%)** |
| 1 | I feel ethics committee should review ethical issues only | 42 (52.5) | 18 (22.5) | 20(25) |
| 2 | I feel ethics committee should review Scientific issues only | 18(22.5) | 22 (27.5) | 40(50) |
| 3 | I feel the role of ethics committee is mandatory in a research institute | 74(92.5) | 5(6.2) | 1(1.3) |
| 4 | I feel medical research projects require an ethical committee review | 72 (90) | 5(6.2) | 3(3.8) |
| 5 | I feel only well accomplished researchers should be reviewers in an ethical committee | 52(65) | 13(16.2) | 15(18.8) |
| 6 | I feel certain aspects of research design needs more ethical attention than any others | 53(66.2) | 20(25) | 7(8.8) |
| 7 | I feel non-medical members have a significant role in an ethical committee | 38(47.5) | 32(40) | 10(12.5) |
| 8 | I feel a system for monitoring progress in research should be adopted | 66(82.5) | 8(10) | 6(7.5) |
| 9 | I feel ethics committee review delays the research projects | 30(37.5) | 23(28.7) | 27(33.8) |
| 10 | I feel ethics committee should restrict its’ involvement for high risk research only | 24(30) | 18(22.5) | 38(47.5) |
| 11 | 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) |
| 12 | I feel ethics committee is an hindrance to any research project | 7(8.8) | 15(18.6) | 58(72.6) |
| 13 | I feel it is time consuming when ethics committee calls for presentation to full board | 23(28.7) | 27(33.8) | 30(37.5) |
| 14 | I feel documentation required for protocol submission is extensive | 42(52.5) | 17(21.2) | 21(28.3) |
| 15 | I feel annoyed when ethics committee asks queries in my protocol submission | 27(33.8) | 20(25) | 33(41.2) |
| 16 | I feel the submission of closure reports for research projects is unnecessary | 13(16.3) | 23(28.7) | 44(55) |

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.

**Table 2: Association of variables with the attitude score**

|  |  |  |  |
| --- | --- | --- | --- |
| **Variable** | **Group** | **Mean score ± 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 |

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

**Figure 1: Attitude score based on designation of participants**

**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 [7, 8] and also an Indian study by Mallela *et al* which reported that 96.2% of respondents had accurate knowledge about Ethics committee. [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.

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 (ICMJE) 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 let 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 fail 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].

**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.

**Limitations:**

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

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