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Research Article

PERCEPTION OF INVESTIGATORS ABOUT INSTITUTIONAL ETHICS COMMITTEE OF A TERTIARY CARE TEACHING HOSPITAL: A QUESTIONNAIRE BASED STUDY

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A B S T R A C T

Purpose: Ethics committee approval is necessary for research proposals to safeguard the dignity, rights, safety, well-being of all research participants. ECs have the responsibility of ensuring ethical compliance in conduct of the study.Whether EC is facilitating or making difficult the conduct of research is sometimes debated. Much has been published on the goals and elements of review by EC, however there are few studies showing perceptions of various stake holders about EC. This study was planned to assess the perception of investigators about EC at a tertiary care hospital.
Material and methods: A cross sectional, questionnaire based survey was conducted in a tertiary care teaching hospital. Respondents were investigators involved in trials in this hospital. Data was expressed as counts and percentages.
Results: 100 % participants were aware about the registration of EC with DCGI. 53.8 % were correct about the primary role of EC. Around 90% participants were satisfied with decision making, protocol review, unbiased nature, maintenance of records, overall working of EC.42 % participants felt the need for separate scientific committee for protocol review.
Conclusion: The investigators of this institute are satisfied with the working of EC.

INTRODUCTION

Research involving human subjects must be reviewed by a committee called an Institutional Review Board (IRB) or Institutional Ethics Committee (IEC).The top priority of an EC is human subject protection. It is necessary for all research proposals on biomedical, social and behavioral science research for health involving human participants, their biological material and data to be reviewed and approved by an appropriately constituted EC to safeguard the dignity, rights, safety and well-being of all research participants [(1)].In accordance with various guidelines like Declaration of Helsinki (World Medical Association, 2013), the Belmont Report (Belmont, 1979) etc. IEC/IRB came into existence [(2)].IEC approval is required by regulating bodies like DCGI for conducting research involving human subjects. IECs are entrusted with the initial review of research proposals prior to their initiation, and also have a continuing responsibility to regularly monitor the approved research to ensure ethical compliance during the conduct of research[(1)]. Charged with the responsibility of safeguarding the rights and welfare of research subjects, IEC's determine the level of participation risk, assess adequacy of informed consent, ensure adherence to research protocols, and monitor for adverse outcomes [(3)]. ECs have been performing the task of local regulator for clinical trials which are being conducted at sites ensuring ethics and data quality, thereby providing Human Subject protection and adherence to Good Clinical Practice[(4)].

The question whether the ethics committee is facilitating or making difficult the conduct of research is sometimes hotly debated [(5)].Several studies have suggested that researchers lack confidence in the quality of IRB reviews [(6,7)].Literature also shows that researchers in all countries have varied perceptions about review done by EC. These views are often shaped by personal experiences with IRBs, and misperceptions are not uncommon [(8)]. IRBs have been described as unpredictable, inconsistent, inefficient, to their original intention, and dysfunctional [(9,10,11)].Ethical guidelines have existed since a long time but still many ECs are struggle with issues like inadequate or no standard operating procedures (SOPs), non-compliant constitution of EC, irregular schedule of EC meetings, improper record keeping and archival, no processes in place for different types of review [(12)].Much has been published on the goals and elements of review by IEC,

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however there are a very few studies showing perceptions of various stake holders about IEC. This study was therefore planned with the objective to assess the perception of investigators about IEC at a tertiary care teaching hospital in central India.

Objective

To assess the perception of investigators about IEC at a tertiary care teaching hospital.

MATERIAL AND METHODS

Study design: This was a cross sectional, questionnaire based survey conducted in a tertiary care teaching hospital in central India after approval from the Institutional Ethics Committee.IEC of this tertiary care teaching institute reviews clinical trials, biomedical and health research and is registered with Central drug standard control organization as well as Department of health research. Respondents were primary investigators or co-investigators involved in regulatory or academic trials in the same tertiary care teaching hospital. They were explained the nature and purpose of the study and necessary consent was obtained.

The study instrument was a self- developed, pre-validated semi-structured questionnaire consisting of both open and close-ended items. The questionnaire was first pretested in 5 participants and suitable modifications done. Final version of the questionnaire was distributed to 52 respondents. Appropriate instructions about filling the questionnaire were given. Identity of the participants was not revealed. Participants were given one hour to complete the questionnaire. The questions were mostly related to the functioning of the IEC. Data was expressed as counts and percentages.

RESULTS

A total of 52 responses were analyzed.
Investigator's knowledge about IEC

All the participants that is 100% were aware of the fact that the Institutional ethics committee of this institute is registered with DCGI and the composition of the Ethics committee is as per DCGI regulation. When asked if there is separate scientific review committee, 76.92% of participants answered that there is no separate scientific committee. When enquired about the EC's primary role, we received 38 responses. Twenty-eight (53.8%) of them were of the opinion that safeguarding and protecting the interest of the rights and interests of the trial participants is the primary role of the ethics committee. While 10 participants had different opinions about the primary role of ethics committee like permitting the conduct of clinicaltrial, to maintain discipline in medical practice, monitoring of clinical trials etc.

Investigator's perceptions and opinions about the institutional ethics committee. When asked about the need for institutional ethics committee in the institute, 96.15% of the respondents felt that the institute should have ethics committee. Twenty-two participants that is 42.3 % felt that there is a need of separate scientific review committee and ethics review committee. Hundred percent participants responded that their ethics committee reviews protocol in a timely fashion and conducts careful and complete review of protocols. Similarly all the participants (100%) were of the opinion that IEC is fair in decision making, monitors the progress of each approved research project in line with guidelines and SOP and works with investigators to find mutually satisfying solutions in case of disagreement. Ninety six percent participants felt that EC gives complete rational for disapproval of protocols and 3.84% felt that IEC queries regarding consent form are irrelevant. Whereas very few participants (3.83 %) were of the opinion that IEC members hold biases against particular research topic or individual.

When asked if IEC member abstains from protocol evaluation in case of conflict of interest, 46.15% gave apositive response. Ninety six percent participants felt that EC takes timely action when principal investigator has violated its decision. Forty eight participants opined that IEC has been allocated sufficient resources to carry out its function. All the participants agreed to the fact that IEC maintains records accurately, understands protocols adequately and does its job well.

DISCUSSION

This study was conducted to assess the knowledge and perception of investigators about ethics committee at a tertiary care teaching institute in central India. Some of the key considerations identified by all respondents include the need for an EC in the institute to review all human research protocols. Hundred percent response about this was really encouraging and this shows the awareness amongst the investigators about the need of EC. In a study by N.Sultan (2011) significant majority (62.4%) of researchers felt that a committee, like an IRB, is always needed to review human subject's research protocols under all circumstances [13].Almost 53.8% of the investigators were aware of the primary role of Ethics committee that is safeguarding and protecting the interest of the rights and interests of the trial participants. While 10 participants had different opinions about the primary role of ethics committee like permitting the conduct of clinicaltrial, to maintain discipline in medical practice, monitoring of clinical trials etc. According to the ICMR guidelines 2017, research on human participants pertains to a broad range of scientific enquiry aimed at developing generalizable knowledge that improves health, increases understanding of disease and is ethically justified by its social value. Every research has some inherent risks and probabilities of harm or inconvenience to participants/communities. Therefore, protection of participants should be built into the design of the study. Similar inspiring responses (100%) were obtained from the investigators for the considerations like IEC is fair in decision making, monitors the progress of each approved research project in line with guidelines and SOP and works with investigators to find mutually satisfying solutions in case of disagreement and timely approval of the protocols submitted to it. One study, comparing the IRBs of six institutions that review medical education research, reported variability in the timeliness and consistency of IRB reviews. Several university IRBs state timeliness targets in their standard operating procedures and/or use their own IRB metric to set targets for protocol reviews – ranging from 30 to 60 days [14]. Delays in the review of protocol by IEC may be caused by limitations of the IEC process, for instance, lack of staff for protocol reviews or the limited/unavailability of IEC members, etc. So, the response from the investigators regarding timely approval indicates that the IEC has its own timelines targets in the SOP for doing protocol review. Other positive responses regarding the perception of investigators

about Ethics committee includes accurate maintenance of records and understanding the protocols adequately. These responses particularly reflect the investigators experience about the EC which in turn reflects the proper functioning of EC to the satisfaction of investigator. Therefore, 80.76% of the participants were of the opinion that IEC does its job well. One US survey found that about 26 percent of researchers abandoned potential research because they thought that the IRB would not approve their study and 75 percent said that IRB review of research enhanced the protection of research participants and 66 percent believed that IRBs strengthened public trust in research [(15)].

In a similar study conducted among scientists in South Africa on their experiences with ethics review, 42.6 percent indicated that their experiences were negative, whereas others described mixed experiences; only a minority (21.3%) stated that their experiences with IRBs were positive [(16)].From these studies it can be said that some researchers view their IRB experiences as helpful, whereas others see IRBs as an impediment to research.

The present study also shows that all investigators are well aware of the regulations and knew that institutional ethics committee is registered with DCGI as required by our regulating authorities and is constituted accordingly. An EC that works independently and is competent enough to take the ethical decisions is an empowered EC. Only empowered ECs are the ones that can raise the standard and validity of the review process and ensure the protection of participants in human research [(17)].It is also evident from the study that investigators are aware of the fact IEC take timely action when P.I has violated its decision or when scientific and ethical misconduct is alleged, and queries raised by EC for informed consent are relevant.

Without an analysis of the ethical quality and working of ethics committees the institutions, institutional ethics committees, regulators, and the various stakeholders will find it very difficult to know if the intent of regulations is being realized[(12)].Overall the perception of investigators in this study about the ethics committee functioning and their knowledge about EC are very encouraging. However we recognize some limitations of our study that is small sample size and the questions represent only basic information that investigator should be expected to know about ethics committee. Also the participants were not enquired about their experience of working with other IECs if they had any. Despite these limitations, our study reveals important information that is acceptance of IEC among the investigators of this institute.

CONCLUSION

The present study concludes that the investigators at this institute are satisfied with the working of Ethics committee which is required and very important for conduct of clinical research and there appears to be an acceptance of ethics committee among the investigators.

Table 1 Investigator's knowledge about Institutional Ethics Committee

Sr. No	Question	No. of Respondents (%)		
		Yes	No	No response
1.	Is the ethics committee of your institute registered with DCGI?	52(100%)		
2.	Is there a separate scientific review committee in your institute?	12(23.07%)	40(76.92%)	
3	Is the composition of ethics committee of your institute as per the DCGI regulation?	52(100%)		

Table 2 Investigator's perceptions and opinion about IEC

Sr. No	Question	No. of Respondents (%)		
		Yes	No	No response
1	Is there a need for institutional ethics committee in your institute?	50(96.15%)	2(3.84%)	
2	Is there a need of separate scientific review committee and ethics review committee?	22(42.30%)	30(57.69)	
3	Does your IEC review protocols in a timely fashion?	52(100%)		
4	Does your IEC conduct a careful and complete review of protocols?	52(100%)		
5	Does your IEC gives a complete rational for disapproval of protocols?	50(96.15%)	2(3.84%)	
6	Do you feel IEC queries regarding inform consent form are relevant?	50(96.15%)	2(3.84%)	
7	Do you feel that IEC member hold biases against particular research topic are individual?	2(3.84%)	50(96.15%)	
8	Is IEC fair in its decision making?	52(100%)		
9	Does IEC work with the investigators to find mutually satisfying solution whenever disagreement between IEC and P.I exist?	52(100%)		
10	Does IEC member abstain from evaluating the protocol whenever apparent or a real conflict of interest exist?	24(46.15%)	22(42.30%)	6(11.53%)
11	Does IEC monitors the progress of each approved research project in line with guidelines and SOP?	52(100%)		
12	Does IEC take timely action when P.I has violated its decision?	50(96.15%)	2(3.84%)	
13	Does IEC take timely action when scientific and ethical misconduct is alleged?	50(96.15%)	2(3.84%)	
14	Has IEC been allocated sufficient resources to carry out its function?	48(92.30%)		4(7.69%)
15	Does IEC maintain accurate records?	52(100%)		
16	Do you feel that your IEC usually understands your protocols adequately?	52(100%)		
17	Do you feel your IEC does its job well?	42(80.76%)	2(3.84%)	8(15.38%)

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