

**Original Article (Research Article)****Perceptions of Ethics Committee Secretaries on support provided for Ethics Committees' administration & functioning: A Questionnaire based survey**

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Dr. Kumardeep B PaulEmail: kumardeep.paul01@yahoo.in, Mob No: +918451002269**ABSTRACT**

This questionnaire based study to explore the perceptions of Ethics Committees' (EC) Member Secretaries (MS) on the support provided for proper administration & functioning was conducted over 2 months in Mumbai. 54 randomly selected ECs and the respective MS were sent a copy of the pre-validated questionnaire. Efforts were made to get the forms within 8 days. Only 38 ECs participated in the survey. Most (28/38) conduct meetings in a separate room, though 22 ECs have a separate area for archival of their documents with restricted access. 32 MS were content with their support staff and the logistics provided. Guidelines pertaining to the required EC-exclusive office, area for the same, necessary support staff and logistics to be provided should be issued without which the EC functioning would falter. A fully-equipped EC will definitely pave the way for a fully-functional EC.

Keywords: *Member secretaries' role, EC administrative burden, Frequency of EC meetings, Training of EC personal, Ethics Committee Functioning, EC Guidelines and SOPs.*

INTRODUCTION

Any research involving human subjects carries a moral responsibility to ensure the welfare and safety of the subjects. The Ethics Committee (EC) plays a pivotal role in health research. It serves with the motive to gain knowledge about the human condition in relation to its social and natural environment. In their deliberations, the EC is expected to safeguard the dignity, rights, and wellbeing of all actual or potential research participants and in compliance with the Ethical

principles of Biomedical Research by Indian Council of Medical Research (ICMR), 2006^[1,2].

The performance of an Ethics Committee purely relies on its composition. The number of persons in an EC should be limited to 8-12 members. A minimum of 5 persons is required to form the quorum without which a decision regarding the research should not be taken. The committee members should be a mix of medical/non-medical, scientific/non-scientific including lay persons as well. The EC appoints from amongst itself a

Chairman who should be from outside the Institution and not head of the same institution (to maintain the independence of the EC). The Member Secretary should be from the same institution and is essential to conduct the business of the EC^[3]. Thus, it is the Member Secretary who looks after the administrative aspect of the EC which includes organizing meetings, maintaining records and communicating with all concerned. The Member Secretary indeed forms the crux of the Ethics Committee.

The ICMR and the World Health Organisation (WHO) carried out a survey on the functioning of Ethics Committees in 2001 and 2003, involving about 250 institutes all over India. The survey used 20 questions to gather data on the functioning of various ECs and identified some deficiencies. However, the data did not include the perceptions of Member secretaries with respect to the proper functioning of the EC^[4].

Issues regarding the administrative hassles experienced by Member secretaries were also highlighted by certain articles. Kandhari R in 2013 published an interesting article about the intense work pressure experienced by EC Member secretaries in New Delhi heightened by the lack of administrative support given by the institution. Member secretaries complained about the lack of a full-fledged office and different levels of clerical staff for functions such as setting the agenda, set dates for meetings, review process, etc. Shortage of manpower and the already overworked EC were said to add to the administrative woes^[5].

Such instances highlight the important issue regarding the intense workload on Member secretaries and the lack of administrative support with its implications on the EC functioning.

In the current study, data were collected from EC Member Secretaries who were direct contributors to the Ethics Committee proceedings. The aim of the study was to explore the perceptions of EC Member Secretaries on the support provided for proper administration & functioning. The data was gathered from Member Secretaries of various Institutional Ethics Committees (IECs) and Non-

institutional Committees (NECs) in Mumbai, India.

MATERIALS AND METHODS

A list was compiled of the registered Ethics Committees involved in health research in Mumbai registered under Central Drugs Standard Drugs Organisation (CDSCO). A contemporary list of all Institutional Ethics Committees (IECs) and non-institutional committees (NECs) was prepared. The ECs were approached for their permission to interact with their Member Secretaries (MS). There are 50 IECs and 13 NECs in Mumbai. Therefore, the total number of member secretaries are approximately 63. Assuming 95% confidence interval, with an alpha error of 5%, a sample size of 54 was calculated. (Calculated using www.surveysystem.com/sscalc.html). Thus, a total of 54 ECs were randomly selected using a computer generated randomization table from the list of ECs in Mumbai. Contact with EC member secretaries was initiated in March 2016 and the survey was completed in April 2016.

This was a cross-sectional questionnaire-based study. Based on the themes derived from the qualitative data and responses from the six interviews conducted prior to this study, a self-administered questionnaire was developed for this study. It was designed to be user-friendly consisting of 12 multiple choice and polar questions grouped under 4 headings: conduct of EC meeting, space for EC, EC staff and logistics/equipment.

Fifty-four Member Secretaries were sent the hard copy of the questionnaire. They were further contacted over telephone and the purpose of the study was explained to them along with their role in the study. Member secretaries who raised any queries about the questionnaire were provided with clarifications over telephone. Those members who preferred a soft copy were also sent an email bearing the questionnaire. They were all requested to return the completed form within 8 days. A reply-envelope bearing the address of the principal

investigator was also provided along with the questionnaire.

On failing to return within the stipulated 8 to 10 days, the members were reminded by an email and also over telephone subsequently. Efforts were made to get the completed forms in time from the members and those who did not return even after subsequent reminders were assumed to be either not interested in the study or not able to participate due to lack of time or other important commitments.

The responses obtained as data were represented as numbers.

RESULTS

Out of the 54 member secretaries representing 54 ECs in Mumbai city, 38 participated in the survey. This included 26 IEC and 12 NEC secretaries. Out of 16 secretaries who were not included, 10 did not return the forms and 6 forms received were incomplete. The forms were sent by post and collected & analysed over a time period of 2 months (March 2016 & April 2016).

The responses to 6 multiple choice questions and 6 polar questions (12 questions in all) grouped under 4 headings were noted. The data thus acquired, were represented as numbers.

The responses obtained with respect to conduct of EC meeting are shown in Table 1.

Table 1: Conduct of EC meeting:

Conduct of EC meetings	N = 38
1. Frequency of meetings	
• Once a month	5
• Once in 2 months	5
• Once in 3 months	28
2. Place to conduct EC meetings	
• Separate room	38
• Any room	–
• Others	–
3. How often asked to conduct meeting in another place?	
• Frequently	–
• Sometimes	11
• Never	27

Most of the EC meetings are conducted once in 3 months (28/38). These meetings are conducted in

a separate room and most of the Member secretaries have never been asked to conduct the meetings in another place. Sometimes the meetings may be rescheduled to some other place due to certain other important reasons (11/38).

The responses obtained with respect to the space provided for EC are shown in Table 2.

Table 2: Space for EC:

Space for EC	N = 38
1. EC-exclusive office	
• Yes	15
• No	23
2. EC office area	
• < 100 sq. ft.	16
• 100 – 200 sq. ft.	5
• 200 – 400 sq. ft.	12
• > 400 sq. ft.	5
3. Adequate space provided	
• Yes	27
➤ < 100 sq. ft.	5 (n = 27)
➤ 100 – 200 sq. ft.	5 (n = 27)
➤ 200 – 400 sq. ft.	12 (n = 27)
➤ > 400 sq. ft.	5 (n = 27)
• No	11
➤ < 100 sq. ft.	11 (n = 11)
➤ 100 – 200 sq. ft.	–
➤ 200 – 400 sq. ft.	–
➤ > 400 sq. ft.	–
4. Separate area for archival of EC documents	
• Yes	22
• No	16
5. Restricted access for EC	
• Yes	22
• No	16

23 of 38 ECs do not have a dedicated office; 12 of these 23 ECs were satisfied with the arrangements. The rest 15 ECs with a dedicated office are satisfied with the space provided.

Of the 27 Member secretaries content with the space provided, 12 have a space of around 200-400 sq. ft. There were 5 ECs who were pleased with the allotted office space of < 100 sq. ft. area. Around 22 ECs have a separate area for archival of their documents with restricted access.

The responses obtained with respect to EC staff are shown in Table 3.

Table 3: EC Staff:

EC Staff	N = 38
1. Number of support staff	
• None	5
• 1 staff	23
➤ Clerk/Typist	5 (n = 23)
➤ Peon	5 (n = 23)
➤ Research Officer	6 (n = 23)
➤ Secretary to Director	7 (n = 23)
• 2 staff	5
➤ Clerk/Typist	5 (n = 5)
➤ Peon	5 (n = 5)
• ≥ 3 staff	5
➤ Clerk/Typist	5 (n = 5)
➤ Peon	5 (n = 5)
➤ Executive member	5 (n = 5)
➤ Research Officer	5 (n = 5)
➤ Secretary to Director	5 (n = 5)
➤ Co-ordinator	5 (n = 5)
2. Details of support staff *	
• Clerk/Typist	15
• Peon	10
• Executive members	5
• Research Officers	11
• Secretary to Director	17
• Co-ordinators	5
3. Adequate support staff	
• Yes	32
➤ No staff	5 (n = 32)
➤ 1 staff	17 (n = 32)
➤ 2 staff	5 (n = 32)
➤ ≥ 3 staff	5 (n = 32)
• No	6
➤ No staff	–
➤ 1 staff	6 (n = 6)
➤ 2 staff	–
➤ ≥ 3 staff	–

*Some ECs have more than one staff members

32 secretaries were content with the support staff available, of which 5 of them did not have any support staff. Six secretaries had one support staff member in their EC and were not satisfied with it. 23 ECs have at least one support staff and five ECs reported two support staff including one clerk/typist and one peon. Five ECs have more than three staff members which includes a clerk/typist, peon, executive member, research officer, secretary to director and a co-ordinator each.

The responses obtained with respect to the logistics/equipment provided for EC are shown in Table 4.

Table 4: Logistics/Equipment:

Logistics/Equipment	N = 38
1. Equipment provided	
• Desktop/Laptop	38
• Phone	32
• Printer/Scanner/Copier	38
• Internet facility	32
• Shredder	10
2. Adequate logistics/equipment	
• Yes	32
➤ Desktop/Laptop	32 (n = 32)
➤ Phone	32 (n = 32)
➤ Printer/Scanner/Copier	32 (n = 32)
➤ Internet facility	32 (n = 32)
➤ Shredder	10 (n = 32)
• No	6
➤ Desktop/Laptop	6 (n = 6)
➤ Phone	–
➤ Printer/Scanner/Copier	6 (n = 6)
➤ Internet facility	–
➤ Shredder	–

A desktop/laptop and a PSC (printer, scanner, copier) was available with all the secretaries. Many secretaries (32 each) also had telephone connection and internet facility. Few of them (10 secretaries) had a shredder too.

Likewise, 32 secretaries from among the 38 secretaries were comfortable with the equipment provided to them as opposed to six secretaries who were not satisfied despite having a desktop/laptop and a printer.

DISCUSSION

Majority of the Member secretaries representing various ECs of Mumbai had similar opinions regarding support provided to them for proper functioning of their respective ECs.

Member secretaries form a very important role in the proper functioning of the Ethics Committee. Their responsibilities are varied with respect to general administration and management of EC, conduct of EC meetings, record keeping, conduct review procedures and take decisions accordingly, etc ^[1]. Though certain SOP (Standard Operating Procedures) do mention the role and the responsibilities of Member secretaries, not much has been written about the support provided to them to carry out their work ^[3]. The perceptions of Member secretaries in Mumbai on support

provided for EC administration have not yet been summarized in any journal, to the best of our knowledge.

Hence, a questionnaire based study was planned and responses of 38 Ethics Committee Member Secretaries in Mumbai were subsequently studied to understand their perception and expectations regarding the support and aid provided to them.

A. Conduct of EC meetings

The cardinal role of EC is to review every research proposal on human participants before the research is initiated. The onus of screening these proposals for their completeness and classifying them into three possible risk types, viz. exemption from review, expedited review & full review, lies with the Member secretary^[1,3]. The Member secretary does so by categorizing the proposals into those involving less than minimal risk (involving educational practices), no more than minimal risk (involving clinical studies of drugs & medical devices, adverse events or disasters) and more than minimal risk (involving collection of clinical data through invasive & non-invasive procedures, etc.) respectively^[1,2,3].

The SOP (Standard Operating Procedure) of an EC should specify the review period for a project. The ICMR SOP states that EC meetings should be conducted at regular intervals and they should not keep a decision pending for more than 3-6 months^[1,3]. For that, the Member secretary should schedule EC meetings at frequent intervals depending on the number of projects or proposals that need to be reviewed.

As per our results, most of the EC meetings in Mumbai are conducted once in every 3 months. The frequency of these meetings may vary from one EC to another due to the reasons stated above. Though, all the EC meetings in Mumbai are conducted in separate rooms, sometimes the meetings are held in some other place on behest of some other important meeting. A room should be allotted by the institution/management for the EC meetings to take place. EC members are acquainted with the place where the meetings are

conducted and unnecessary hassles/delays are avoided due to frequent changes in the venue. As per our study, most of the ECs do not need to make changes in the venue to conduct EC meetings.

B. Role of secretaries in decision making and the logistics/equipment provided

A subsequent decision is usually taken by a broad consensus in these meetings so as to recommend/ reject/ suggest modifications for a repeat review or accordingly advise appropriate steps^[1].

The Member secretary is required to communicate the decision in writing to the PI (Principal Investigator). Any amendment to the originally approved protocol, serious or unexpected adverse events and subsequent remedial steps or any new information that may influence the conduct of the study must be brought to the notice of the EC. All such incidents should be carefully documented after the Chairperson's approval^[1,2,3]. The entire load of responsibility of documentation, communication with the involved persons, archival of the decisions falls on the shoulders of the Member secretary.

Provision of a desktop/laptop, a telephone and a printer/scanner/copier would definitely go a long way in facilitating the member secretaries in exercising their functions efficiently.

Communication with other members of the EC, communicating EC decisions to the PI would be less laborious with the use of a desktop/laptop, a telephone and internet facility. Tedious and archaic ways of documentation and archival would become easier by using a printer/scanner/copier.

A similar view was observed by many of the ECs in Mumbai, as per our study. Most of them do have logistic support in terms of a desktop or a laptop, internet facility, a printer/scanner/copier and a telephone. It provides a quicker way to communicate with involved persons, to intimate other members regarding the meeting schedules and also to keep the EC and its members updated with respect to newer national or international

ethics guidelines. It also serves an alternate method of archival and documentation where in copies can be scanned and stored in a hard drive. This would ensure larger amount of information requiring lesser storage space subserving the requisite restricted access and safety parameters also.

C. Education and Training

In today's world of ever-changing regulatory requirements, it is necessary for EC members to keep abreast of all national and international developments in ethics. All relevant new guidelines should be brought to the attention of the members ^[1,2,3].

Orientation courses for the same need to be organised by EC and the Member secretaries should take lead in arranging such courses. Similar programs related to Good Clinical Practice (GCP) should also be initiated by Member secretaries to train the EC members to undertake drug trial reviews ^[1,2,3].

Members should be encouraged to attend national and international training programs in research ethics for maintaining quality in ethical review and to be aware of the latest developments in this area.

An internet facility along with a desktop/laptop would serve the purpose of education and training with ease. As per our study, most ECs in Mumbai city do have the provision of a desktop/laptop and internet facility. They are thus expected to be well versed with the national and international ethics regulations and the GCP guidelines as well.

D. Space provided for EC

A full time Member secretary and a space/office for safe-keeping the records is the hallmark of a well-functioning EC ^[1].

In our study, most of the ECs in Mumbai do not have a dedicated office. Also, the space provided to them is not perceived to be adequate for the necessary EC office.

In spite of not having an exclusive office, most of the EC do have a separate area for the proper

archival of their documents and have restricted access for the same.

Although the unavailability of a dedicated office is lamented, the necessary precautions taken by ECs in Mumbai to ensure proper archival of the documents with restricted access must be applauded.

It is the function of Member secretaries to look after the documentation of an EC. Strict confidentiality is to be maintained during access and retrieval procedures. Extensive record keeping forms a prime role of the Member secretary ^[1,2,3].

Records to be safeguarded are as follows ^[1]:

- 1) Constitution, composition & SOPs (Standard Operating Procedures) of the EC;
- 2) CV (Curriculum Vitae) of all EC members with records of training if any;
- 3) National and International guidelines;
- 4) Copies of protocols submitted for review;
- 5) All correspondence with EC members and investigators regarding application, decision and follow up;
- 6) Agenda of all EC meetings;
- 7) Minutes of all EC meetings with the Chairperson's signature;
- 8) Copies of decisions communicated to the applicants;
- 9) Record of all notification issued for premature termination of a study with a summary of the reasons;
- 10) Final report of the study including microfilms, CDs and Video recordings.

It is recommended that all records must be safely maintained after the completion/termination of the study for a period of at least 3 years if not more, due to resource crunch and lack of infrastructure ^[1,3].

E. Support staff

It is imperative that adequate support staff be provided to Member secretary as an aid to his/her manifold functions. Our study shows that most of the ECs in Mumbai do have at least one support staff member to help the Member secretary in

their work. Some of the ECs have two and few others have more than three full-time support staff for the EC functions.

Member secretary is selected from the parent institution of which the EC is a part. Thus, he/she has to advocate dual roles in the working of the institution. A full-time support staff in the form of a clerk, typist, research officer, co-ordinator, etc. will definitely aid in the EC administration and working. Moreover, it will also enhance the proficiency of the EC.

Every institution should allocate a reasonable amount of funds in form of support staff and logistics for smooth functioning of the EC ^[1]. Such valuable assistance by the institution will pave the way for an effortless and a more efficient EC.

CONCLUSION

The current study asserts the opinions of Member secretaries of various Ethics Committees with respect to the support provided for EC administration. Although, SOP of different ECs have varied instructions for the functions of the Member secretaries, there are no proper guidelines for their administrative support. Guidelines pertaining to the required EC-exclusive office, area for the same, necessary support staff and logistics to be provided should be issued. ECs performing without an exclusive office or support staff would falter regarding proper documentation and archival. This may eventually have an adverse effect on the efficiency of the EC functioning. These guidelines would definitely provide an impetus to improve the working of the EC comprehensively. They would also aid national as well as international regulatory bodies in their surveys on the overall functioning of ECs. Although the study was conducted in a limited number of ECs in Mumbai, most of the secretaries were of similar views regarding the in/adequacy of support provided to them for their EC functions. A similar study done at a larger, nationwide scale would definitely benefit ethics regulatory bodies in India and elsewhere so as to

improve the working efficiency and ease of member secretaries and in turn the ECs as well.

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