ORIGINAL ARTICLE
IDENTIFYING THE BARRIERS BETWEEN RESEARCHERS AND ETHICAL REVIEW COMMITTEE: A PILOT STUDY

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Background: Approval from Ethical Review Committee (ERC) has often been considered a challenge by researchers. Regular evaluation of ERC procedures has been recommended globally. We have evaluated working of ERC at Foundation University by identifying gaps between ERC and researchers with the vision to improve the efficiency of the committee. **Methods:** A cross sectional study was conducted, after permission from president ERC. We developed a structured feedback proforma with 20 questions regarding application form, its processing and over all experience of researchers. A total of 65 volunteer faculty members who had ever applied to ERC for approval, participated in study. A descriptive analysis was done using spreadsheets. **Results:** Out of 65 volunteers, 41 returned and completed the proforma. More than 50% (n=24) respondents considered application form was simple to comprehend, however, 40% (n=17) agreed that ERC should provide assistance in its completion. The good majority received final approval letter within one month of application however almost none received proper acknowledgement of receipt and notification of time taken for review. Two third participants (66%, n=27) showed confidence in ERC decisions. Improvement in communication between ERC and researchers through IT support was suggested. **Conclusions:** Researchers agreed that ERC at Foundation University with its limited resources was fulfilling its role of timely review process and showed confidence in its decisions. The communication lack between ERC and researchers was considered major weakness.
Keywords: Eethical rreview process, communication gaps, researchers' feedback

INTRODUCTION

The basic purpose of Ethical Review Committee (ERC) is to protect the rights of the human participants involved in research. Where necessity of ERC is undeniable, equally undeniable is the discomfort of the researchers and their sense of grievance towards the ERCs.[1] Whether the root cause of this discomfort is the perceived loss of freedom,[2] the frustration due to delay in the process of review especially in a multicentre study[3], the resentment towards the patronising and complacent attitude of the ERC reviewers[4] or the sense of despair at the apparent obtuseness of the ERC members towards the technical details and urgency of the proposed research project[5]. It is well worth the effort to investigate it as it culminates in researchers being wary of ERC and non-compliant with its recommendations.

Globally, regular evaluation is recommended for quality assurance and working of ERC for better future outcomes including researchers satisfaction[6]. Assessment of ERC performance can be done through development of various standard operating procedures, self-assessment tools and critical feedback from researchers[1]. In our previous study we have evaluated the functioning of ERC at Foundation University through development of a structured Constitution-Practice-Outcome (CPO) self-assessment tool.[7] In continuation of our previous work, current study was planned to further evaluate working of ERC at Foundation University and to explore weaknesses in application form, its processing and ERC decisions as reflected by researchers at Foundation University through their feedback with a vision to improve our functioning.

METHODOLOGY

The Department of Physiology at Foundation University Medical College, Islamabad provides support to secretariat office of ERC in carrying out its administrative affairs since 2011. A cross-sectional pilot, semi-structured questionnaire-based, descriptive study was carried out at the Department following permission from president ERC.

On the basis of literature review[8–12], a structured feedback proforma was developed for researchers to respond and evaluate various aspects of ERC working at Foundation University. The proforma included both closed and open ended questions. The 20 item proforma constituted of three basic parts. Firstly, with questions regarding ERC application form, second with questions to identify barriers in the application processing and third with open-ended questions regarding the overall experience of researcher with ERC. The rating options were mostly Yes/No/Not sure. In the end space was provided to give suggestions to improve ERC working. Proforma's were distributed among all departments of constituent colleges of Foundation University. From each department, faculty and post graduate students who had ever applied for ethical approval were asked to participate in this study on volunteer basis. Those who did not want to

participate or never had any sort of correspondence with ERC were excluded. Informed consent was taken from all the participants and their identities were kept confidential. A total of 65 faculty members of Foundation University volunteered. The participants were asked to recall their experience with ethical review process before responding to questions. Their experience could include filling application form, time taken in review, types of responses received, trust in ERC decisions, difficulties faced in contacting ERC or any other barriers in obtaining ethical approval from ERC.

Open ended questions included the opinion and suggestions to increase effectiveness of ERC and for critical analysis of researcher's view point about the working of ERC. The returned responses were checked for completeness of data. The data was analysed on MS Excel 2016. Descriptive statistics were used to present the data in the form of frequencies and percentages.

RESULTS

Out of 65 faculty members who volunteered to participate in this study, 43 responded from which 41 were found to have complete data. All respondents had applied for ethical approval through delivering the application in person to the ERC secretariat. Only one applicant applied through email. Questions regarding ERC application form were considered simple to comprehend by 22 (54%) of participants and 25 (60%) agreed that sufficient information was given in the form to fill it properly. However, about 40% (n=17) participants also agreed that ERC secretariat should assist in filling the application form.

In the second part of the proforma where questions regarding application review process were asked, it was found that more than 85% (n=36) participants were not aware of availability of expedite review option for descriptive type of studies. Only less than 15% (n=6) were aware of the option and 2 (4%) participants had availed it who received response within one week time on average. Rest of the responses were received within one month duration.

More than 90% (n=38) researchers were not informed by any means (i.e., verbally, via letter or through email) about the receipt of ERC application and the time that would be taken for review by the ERC secretariat. Almost 72% (n=30) were satisfied with ERC responses and considered that the comments were justified. More than 80% (n=34) received ERC approval notification as official letter signed by president ERC; 3 faculty members did not receive any notification at all.

In the third part of proforma where overall experience with ERC was explored, it was revealed that more than two third participants (27, 66%) were satisfied with ERC performance and showed trust in its decisions. More than half of the participants were not sure if the written goals and purposes provided on the website for researchers were clearly stated. Only 11 researchers provided suggestions to improve ERC working with a common theme of improving online submission process, arranging workshops on bioethics so that researchers could be better aware of ERC requirements and arrangement for improvement in communication with ERC.

DISCUSSION

Ethical review committees ensure that progression and addition of knowledge to life sciences is not at the cost of human dignity and safety. Studies done after appropriate ethical review are accepted and acknowledged well all around the globe.[13] Ethical committees all over the world entail constant development and improvements in their procedures based upon user dissatisfaction.[14] Lack of clarity concerning the framework and working of ERC is one of the main causes of growing tension between researcher and ERC.[8] Most researchers consider getting ethical approval as lengthy and challenging procedure.[9]

Current study was done to evaluate working of ERC at Foundation University by exploring its strengths and weaknesses as reflected by researchers through their feedback with a vision to improve its functioning. Efficiency of the ERC can be enhanced by improving the procedures, refining the ethical approval forms and training of the ERC members.[1,3,7] Keeping this in mind, feedback proforma was developed to evaluate ERC form, review process and researchers overall experience.

It was found that only 54% participants considered application form as easy to fill in and more than 40% agreed that they should be provided assistance to comprehend it. This finding seems to coincide with views of Jon Nicholl[8] who criticizes the application forms by denoting them as 'mind boggling forms' to be filled in with bureaucratic unhelpfulness of committees. ERC form can be simplified as per ERC working guidelines. However, necessary information regarding the design and conduct of the study, the method of recruitment of research participants, storage arrangements for human tissue and other relevant materials, the care and protection of research participants, the right of research participants to withdraw from study, the protection of research participants' confidentiality, proposed arrangements for the retention of records, the consent process and any community considerations both within and external to the University cannot be omitted.[14] All this necessary information does make the form inevitably lengthy and is considered as hassle by the researchers.

Often researchers complain about firm and extended procedures resulting in delaying their research rather than expediting it.[9] In the current study, it was encouraging to find that the approval of research proposals from the ERC on average was received within a month in majority of participants. This is contrary to

findings in other studies where time taken for approval varied from 6 to 208 days.[10] In this regard the efficiency of the committee is remarkable. It was however, alarming to find that majority of researchers were unaware of availability of expedite review request option. Also, only 'verbal' acknowledgement of the receipt of research proposal and 'no notification' regarding time to be taken for review process showed procedural weakness.

Documented acknowledgement of receipt of protocol and notification of approximate time to be taken for review from ERC secretariat would certainly improve communication and trust between researchers and ERC. Lack of training and time could be the important reasons. The gravity of administrative and IT support in this regard cannot be undermined. In this context, the ethics committee of University of West London states that there is 'a need to increase the support capacity for Research Ethics Committees. Such support includes dedicated administrative support, access to training, and access to specialist knowledge, IT support systems, and dedicated time for participation on Research Ethics Committees'.[14]

In the current study it was motivating to find that more than two third of participants who had applied for ethical approval were satisfied with ERC responses and showed trust in the decisions. This was encouraging because often ERCs have been blamed to have been concentrating on only scientific, legal, and confidentiality issues instead of ethical issues.[8–10] Current study participants suggested few modes to improve ERC working which included improvement in communication with researchers especially regarding online submission process and conducting bioethics workshops with them. It is worth mentioning here that online submission process does exist however it was never utilized by the researchers and they preferred to submit in person only. All of this can be due to lack of communication at all levels of the research review process which has also been pointed out by ERC of University of West London. They agreed that resources should be made available to support committees locally and communication needs to be improved at all levels.[14]

This study was the first of its type by ERC at Foundation University. In light of the above findings, ERC secretariat would stress upon the need of better IT and administrative support to improve communication between researchers and ERC members. Next step would be to further identify any barriers between researchers and ERC members by conducting qualitative analysis of discussion with both researchers and ERC members through in depth focus group meetings.

CONCLUSION

Researchers agreed that ERC at Foundation University with its limited resources is fulfilling its role of timely review process and also showed confidence in its decisions. The communication lack between ERC and researchers was considered major weakness.

RECOMMENDATIONS

Online procedures to communicate with ERC should be advocated with IT and administrative support. Regular workshops, seminars and training programmes should be organized to increase awareness about ERC working and to facilitate researchers in writing research protocols. Periodic review meetings need to be organised to improve working of ERC based on feedback.

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