

ORIGINAL ARTICLE

Attitudes and Perceptions about the Research and Ethics Committee in Kampala, Uganda

Charles BR Ibingira, Joseph Ochieng

Makerere University, School of Biomedical Sciences Department of Anatomy, Kampala, Uganda

ABSTRACT

Background

The Makerere University Faculty of Medicine Research and Ethics Committee reviews and approves more than 100 new research protocols a year, yet its activities had never been evaluated as far as the researchers are concerned.

Methods and results

This was a cross sectional study at Makerere University Faculty of Medicine and Mulago Teaching Hospital. The survey population included all staff involved in research at the post graduate level and faculty.

Most of the respondents agreed that decisions of the REC were binding 53 (75.7%), 15 (21%) hold that were variable and 2 (2.9%) biased. The biased attitudes of researchers regarding protocol review reduces as researchers present more protocols to the REC.

Most of the respondents do agree that the REC makes researchers more aware of ethical issues (52.9%), that ethical review is important for protection of human subjects (55.8%), and that the system of ethical review protects human research participants (65.7%). 48.6% believed that the REC ensures that researchers adhere to elements of the consent process which help to protect the autonomy of research participants. However 51% doubt the ability of the REC to ensure that researchers adhere to elements of the consent process during conduct of research

More than 97% of the respondents believe that the REC is either average or very good, while 2.8% rank it below average.

Conclusion

The Research and Ethics Committee sticks to the scientific design and ethical issues to ensure protection of research participants. Some respondents reported bias during review, delay in approval of protocols as well as lack of follow up of on going research.

However, majority of respondents ranked the committee as average or above average.

Keywords:

Medical ethics, Human Research Ethics, Research Ethics Committee, attitudes, Uganda

INTRODUCTION

The purpose of research is to generate or contribute to generalisable knowledge that could benefit present and future generations.¹ And because of the need for research as well as the requirement that all research involving humans as participants should meet at least the minimum ethical standards including the respect for the rights and welfare of human participants, many national and international guideline have been developed to facilitate the conduct of research.¹⁻⁵ It is therefore a requirement that all research involving humans as participants undergoes a process of ethical review and approval before enrollment of participants can commence.

Since Makerere University and in particular the Faculty of Medicine conduct a considerable amount of research, the faculty research and ethics committee has been operational for many year. This research and ethics committee is one of the busiest in the country and reviews and approves over 100 new protocols every year. The committee functions both as a scientific as well an ethics committee hence considers both the scientific merit and ethical standards in addition to continuing review.

However, because of the enormous numbers of protocols for review, sometimes researchers may not be left satisfied with the committee's functions and decisions. It is also known that researchers many times do not appreciate the role of such committees.⁶⁻⁷

Hence there was need to evaluate the functioning of the committee as perceived by the researchers

Objective

To evaluate the attitudes and perceptions of the researchers about the research and ethics committee

METHODS

This was a cross sectional study at Makerere University Faculty of Medicine and Mulago Teaching Hospital. The survey population included all staff involved in research at the post graduate level and faculty.

Corresponding author:

Dr. Joseph Ochieng; MBChB, MSc, MHSc(Bioethics); Lecturer
Makerere University, School of Biomedical Sciences,
Department of Anatomy, P.O Box 7072, Kampala, Uganda

The survey sample was drawn from the Faculty of Medicine staff, and Mulago Hospital clinicians database by simple random sampling. All departments that do research were included. Only researchers who had never served as members of the research and ethics committee were eligible to participate. The data collection instrument was first pre-tested and relevant corrections made before use for data collection.

Following informed consent, the researchers were handed the structured questionnaire for filling at their own convenience. A special box was left at an accessible but safe point in each department where filled questionnaires had to be dropped for the investigator to collect, and this done to ensured protection of privacy and confidentiality of the respondents.

Ethical review and approval was sought from the Faculty of Medicine Research and Ethics Committee. Informed consent was obtained from all the respondents before data collection and appropriate measures were taken to minimise risks and maintain confidentiality.

The data was first analyzed descriptively by SPSS Statistical package; averages for questions that required quantitative answers and frequency tables for questions that required a choice among several given alternatives were calculated, bar graphs and pie charts were constructed. ANOVA was used to test for differences between means of variables on researchers attitudes about the REC and ethical review.¹¹

RESULTS

Seventy responses were recorded out of the 135 researchers consented giving a response rate of 52%. The age range of the respondents was 30 to 61years with a male to female ratio was 1.3 : 1.

Majority of the respondents had had two or more protocols reviewed by the research and ethics committee (REC). Most of the respondents agreed that decisions of the REC were binding 53 (75.7%),15 (21%) hold that were variable and 2(2.9%) biased. Researchers whose protocols were not approved on first presentation felt that the REC was biased in its decisions while those whose protocols were approved on first consideration did not regard the REC as being biased. There were more females who thought the REC was biased though this observation was not significant. The biased attitudes of researchers on the REC regarding protocol review reduces as researchers present more protocols to the REC.

Most of the respondents do agree that the REC makes researchers more aware of ethical issues (52.9%), that ethical review is important for protection of human subjects (55.8%), and that the system of ethical review protects human research participants (65.7%). Also 48.6% believed that the REC ensures that researchers adhere to elements of the consent process which help to protect the autonomy of research participants. However 51% doubt the ability of the REC to ensure that researchers adhere to elements of the consent process during conduct of research

More than 97% of the respondents believe that the REC is either average or very good, while 2.8% rank it below average.

The ratio of male to female respondents was 1.3:1 which gave a relatively good representation of the two groups. (Table 1).

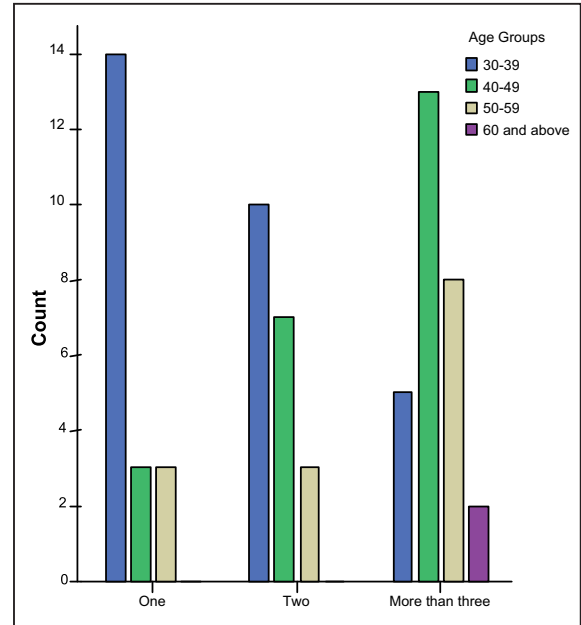


Figure 1. Age groups and number of research protocols reviewed by the REC.

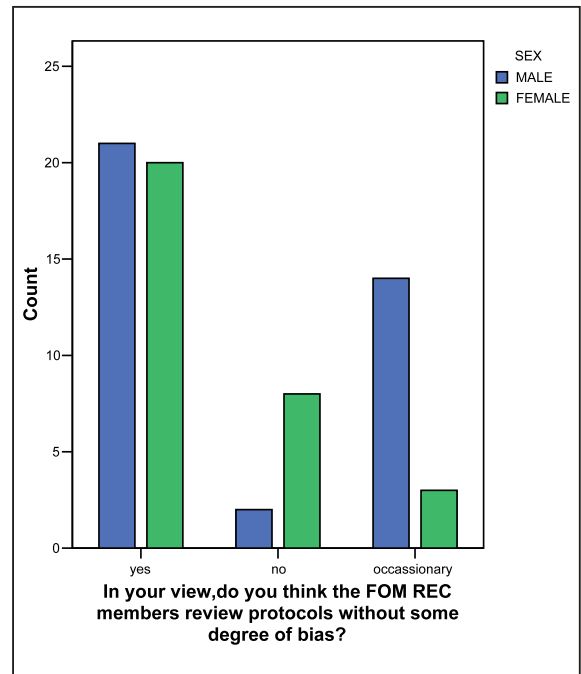


Figure 2. Perception of bias in REC protocol review according to sex.

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	MALE	39	54.3	55.1	55.1
	FEMALE	31	44.3	44.9	100.0
	Total	70	98.6	100.0	

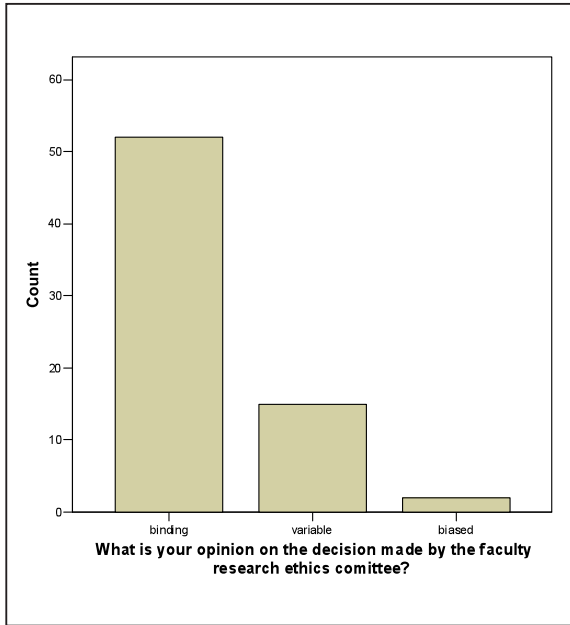


Figure 3. Opinion about decisions made by REC.

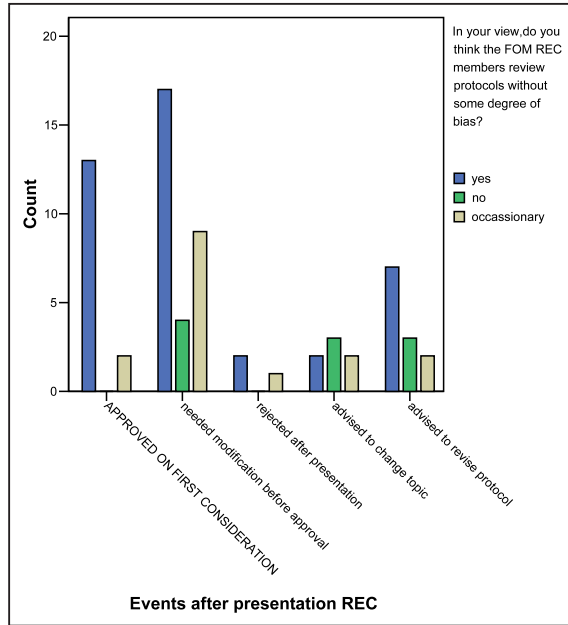


Figure 5. Outcomes of protocol review and perceived biased review by the REC.

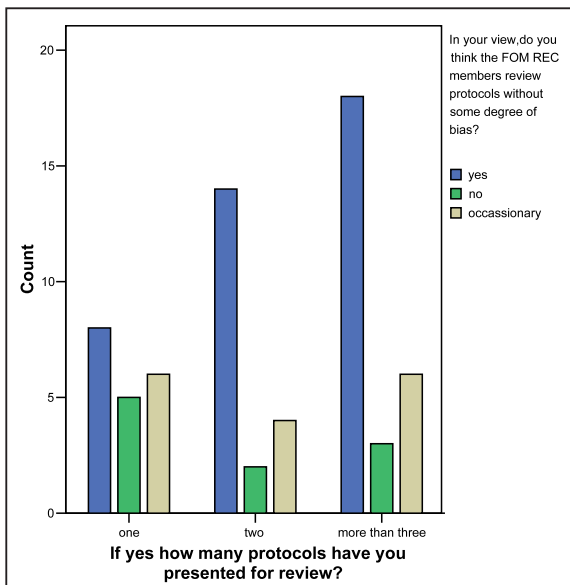


Figure 4. Number of protocols presented to REC and perceived bias towards ethical review.

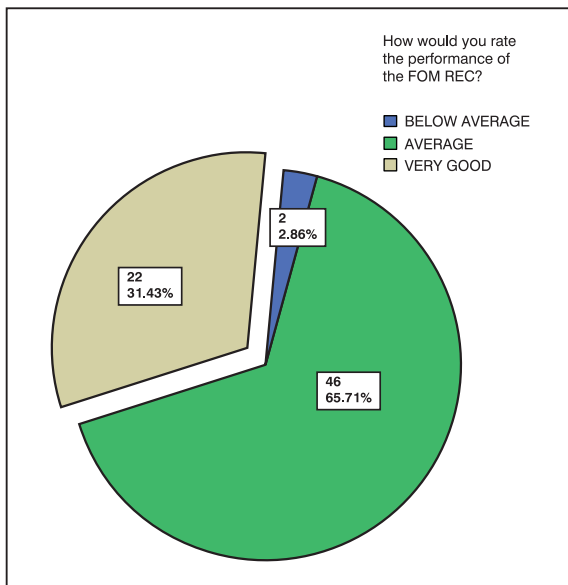


Figure 5. Outcomes of protocol review and perceived biased review by the REC.

		Does the system of review protect subjects {n=70} %Percent	Does the REC make researchers more aware of ethical issues {n=70} % Percent	The REC protection to subjects justify ethical review {n=70} % Percent	The REC ensures adherence to elements of consent process {n=70} % Percent
Valid	Strongly disagree	2.9	8.6	4.3	1.4
	Disagree	7.1	7.1	7.1	18.6
	Not sure	24.3	21.4	22.9	31.4
	Agree	44.3	34.3	32.9	24.3
	Strongly agree	21.4	28.6	32.9	24.3
	Total	100.0	100	100.0	100.0

Although the age range for the respondents was 30-61, its those researchers in the age range 40-49 that have had more than three protocols going through the REC, The majority of participants have had two or more protocols reviewed. Most of the participants were lecturers at the Faculty of Medicine, other researchers from Mulago Teaching Hospital and graduate students participated. (Figure 1).

There were more females who thought the FOM REC was biased as shown in Figure 2.

Most of the researchers agreed that decisions of the REC were binding 53 (75.7%), 15 (21%) hold that were variable and 2 (2.9%) biased (Figure 3).

The biased attitudes of researchers on the REC regarding protocol review reduces as researchers present more protocols to the committee (Figure 4).

Researchers whose protocols were not approved on first presentation, felt that the REC was biased in its decisions, while those whose protocols were approved on first consideration did not regard the REC as being biased (Figure 5).

The majority of the researchers do agree that the REC, makes researchers more aware of ethical issues (52.9%), that ethical review is important for protection of human subjects (55.8%), and that the system of ethical review protects human subjects (65.7%). 48.6% do believe that the REC ensures that researchers adhere to elements of the consent process which help to protect the autonomy of human subjects. However 51% doubted the ability of the REC to ensure that researchers adhere to elements of the consent process during conduct of research (Table 2).

The Respondents hold an attitude that the performance of the REC is average or very good: 46 (66.7%) and 22 (31.4%) respectively. More than 97% of the participants believe that the REC is either average or very good. Only 2.8% rank it below average. It should be noted that the more experienced the researcher the better the rating for the REC (Figure 6).

DISCUSSION

The age ranged from 30 to 61 years and the majority of respondents are in the age group 30-39; this also compares with the ages of the majority staff of Makerere University Faculty of Medicine, and the male to female ratio was 1.3:1, this is almost equal because of the policy of gender balance and women emancipation policy held by the university. Most researchers were lecturers, but because the REC serves the Faculty of Medicine and Mulago teaching hospital researchers from the hospital, graduate students and other affiliated researchers including social scientists were included.

Attitudes of researchers

The attitudes of researchers about the Faculty of Medicine Research and Ethics Committee were reflected in aspect of biased protocol review and review process, decisions, and rating of the usefulness of the REC, many females (80%) feel that the REC is biased. Though this was not very significant probably because of a small sample of survey. However the issue of the REC being biased was reported elsewhere^{6,7}, it was also noted that, some researchers believe that even the final decisions were biased (Figure 3).

However basing on figure 5, it appears that the researchers are also biased about the REC, because where the protocol was approved on the first consideration, it was regarded that

the REC is not biased, and where it was decided that one revises or modifies the protocol before it could be approved the REC was regarded as being biased, although the more protocols the researchers presented to the REC, the less the respondent tended to think that the REC was biased.

These negative attributes may easily occur when researchers cannot see the link between REC actions and the protection of subjects.⁷ Such opinions of looking at the REC as being biased may indicate that researchers, perceive the committee as being unjust, and this should be addressed seriously and carefully because it may be the cause of dishonest behaviour, scientific misconduct, especially when the REC is dealing with researchers with excessive ambition and poor character, on the other hand, and a committee rated or perceived as biased or incompetent, unfair, arrogant or performing below average (Figure. 6) because this could impel some investigators to break rules of ethical science.

Since researchers have invested heavily in their work, so having their work judged as unsatisfactory is likely to be experienced as a personal affront.⁸ And this can be counter productive.^{8,9} Angry, insulted, despised researchers may be more likely to behave in ways that are detrimental to the REC, the institution, and the scientific work.⁷ It is also possible that, while a response rate of 52% remains a limitation, it leaves open the possibility of a non response bias among aggrieved researchers.

It was noted that the more experienced the researcher was, the better the rating of the REC, which implies that with repeated interaction and knowledge of the committee functioning, the better the understanding of the committee's activities. This calls for the committee to publicise itself and educate the researchers about the committee requirements and activities.

Regarding the decisions made by REC, figure 3, most researchers 53 (75.7%) agreed that decisions by the REC were binding, realistic and just. These accept the outcomes of ethical review and put up with the protocol plan, as well as looking up to the REC for guidance in order to uphold and ensure protection of subjects, such a climate, that communicates, justice and fairness to researchers should be retained, so as to deter unethical behaviour of researchers. Further to this is the fact that the respondents gave a fairly positive rating. Where the majority thought REC's performance was average while more than 31% felt it was very good. However, this is not a surprise because REC's at research universities may be better organised and staffed, making researchers rate their own REC's higher than would investigators at other settings.⁷

Ethical Review Process

The majority of researchers appreciate that the REC upholds the elements of protocol review, Table 2, most especially scientific design and conduct of the study (79.7%) which is a requirement by the international ethical codes and the fact that this REC belongs to a university means that the issue of science of the study must be taken very seriously.

Other elements of the review given high rating are ethical issues (75.3%), this entails care and protection of rights and welfare of the research participants (56.5%), recruitment of subjects (51.5%) community considerations (49.9%), confidentiality and informed consent, the fact that the researchers are aware of these ethical requirements is an indication that,

they endeavour to get them achieved, although it was noted that observance of these elements impede research in the U.S.^{3,6,7,10} Respondents also agreed that the REC makes them more aware of ethical issue which is one of its mandates in addition to education of researchers and the community.

However, like elsewhere, researchers feel there is a lot of unnecessary delays in approving proposals, and this could be counter productive by being costly in terms of time and resources. In addition it creates an impediment atmosphere on progress of research as well as demoralising some researchers. All this negative bias can be countered by careful and effective communication. The REC should remain, especially sensitive to the feelings of the researcher, when communicating with them. Particularly if extensive changes are required or if the protocol is not approved. Even criticisms and disappointing news and decisions can be experienced as acceptable if the recipient researcher feels well treated with dignity and given full explanation of the reasons for the negative decision.⁷ Researchers need to be adequately explained to where to change or what went astray.

CONCLUSION

Researchers whose protocols were not approved on first presentation, or where the REC had recommended a major protocol revision before approval still hold a biased attitude about the REC regarding the process of ethical review and the decisions made by the REC. However the more experienced the researchers become the less the perception of bias.

REC sticks to elements of ethical or protocol review, especially, the scientific design, and ethical issues. This ensures protection of Human subjects as well as complying with the international ethical codes. This led to most of the respondents to rank the committee as an average or very good performer.

Finally, the REC still has some flaws according to researchers in relation to bias, delay in approval of protocols as well as lack of follow up of approved and ongoing research.

Recommendations

The FOM REC should improve its publicity, among researchers, by carrying out its mandate of educating researchers, staff and the community about the ethical guidelines for review, and should make greater efforts to educate researchers as a way of limiting the unethical research practices this should be supported by good communication

The REC should employ best practices to endeavour to be a just body that employs fair and just procedures, treating researchers with respect and dignity, accord them an opportunity to have a voice when disagreement occurs or when drastic decisions have been made. Members or administrators of

REC should be trained in skills of interacting with upset or angry researchers.

Organisational policies and procedures that promote the perception of just treatment, should be developed to counter the perception of bias, also the REC members and staff should be involved in a regular self evaluation project, about how the REC perceives itself, compared with how its perceived by its clientele after which, findings could be responded to in a bid to always have an excellent performance and service delivery.

The REC should strengthen its ability to monitor ongoing research to counter the rampant deviations from the required ethical practices. This would require adequate facilitation of REC financially and expertise.

The REC should limit delays in approval of protocols, train the members of REC in research ethics so as to be able to uphold all functions of REC.

Conflict of interest: None declared.

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