



Enhancing Capacity of Research Ethics Review Committees in Developing Countries: The Kenyan Example

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INTRODUCTION

In the last decade, the number of clinical trials being conducted in developing countries has increased tremendously[1] for reasons that include cheaper cost of conducting clinical trials there[2], and the presence of a large and genetically diverse study populations[3,4], among others. The complexity of clinical trial protocols mandates that local ethics review committees (ERCs) reviewing them have the capacity to ensure that they are conducted to the highest scientific and ethical standards. This article describes the process used to enhance the capacity of institutional ERCs in Kenya.

METHODS

Training needs assessment and ethics sensitization seminars.

These were held in different regions of Kenya between July and September 2011. Assessment was conducted using a standard questionnaire aimed at finding out the composition of ERCs, if ERC members had had ethics training, procedures ERCs used to review protocols, among others. Each assessment was followed by an ethics sensitization seminar lasting one day and consisting of lectures on general introduction to ethics, role of ERCs, clinical trials, NCST requirements and guidelines for ERC accreditation and NCST guidelines for ethical review of research proposals. Feedback from participants obtained at end of each seminar was used to improve the quality of subsequent seminars.

Training modules

A training module for ERCs in Kenya was developed using information acquired from the needs assessment seminars. The objectives of the course were to: 1) train members of ERCs on principles of bioethics; 2) train members on Bioethics Guidelines/regulations; 3) provide the trainees with the skills for proposal review; 4) provide the trainees with the skills for Standard Operating Procedures (SOPs) development; 5) form a mentorship program; 6) create a network system of ERCs in Kenya; 7) encourage development of a common data base to reduce potential "ERC shopping" by researchers; and 8) obtain feedback from trainees. Participants were asked to evaluate the training at the end of each workshop. The feedback obtained from the evaluation of the course at the inaugural training workshop was utilized to review and revise the training manual.

Ethics training workshops

Training workshops were then conducted. Topics covered included: 1) basis for ethics; 2) principles of ethics; 3) protection of vulnerable groups; 4) informed consent process; 5) components of clinical trials proposal; 6) legal basis for ethics; 7) role of ethics research committees; 8) development of SOPs; and 9) ethical review process of research proposals.



RESULTS

Training needs assessment and sensitization seminars

Sixteen (89%) of identified ERCs sent members to the needs assessment and sensitization seminar. A total of 111 (72 male and 39 female) ERC members took part. Need for training in the following areas were identified: General introduction to ethics; role of ERCs; accreditation process for ERCs; biomedical Research; pre-clinical & clinical trials; in-depth ERC review process of a proposal; skills for effective execution of mandate by ERC; proposals involving vulnerable groups; and biosafety.

Excess workload was most cited challenge, followed by lack of communication between ERCs. As a result, ERC members felt that it was possible for one ERC to reject a proposal only for it to be approved by another.

Ethics training workshops

Ninety-two ERC members from 13 institutional ERCs have been trained to date as follows: 36 (25 males and 11 females) from institutions in the western part of Kenya, 22 (14 males and 8 females) from institutions in the coastal region, and 34 (19 males and 15 females) from institutions in the capital city of Nairobi. The training workshops are on course, with many more scheduled.

Accreditation of institutional research ERCs

Of the 13 identified un-accredited institutional ERCs at the beginning of the project, 8 have now been accredited by the Kenyan NCST bringing the total number of accredited institutional ERCs to 13.

CONCLUSION

Several training needs of ERC members were identified through a training needs assessment. This was very useful in designing a training module for ERCs in Kenya.

For ERCs to be strengthened, their members need to undergo ethics training. It is also important that ERCs interact with one another in a formal way. This could ensure that a proposal rejected by one ERC is not presented to another ERC for review, thereby preventing the concept of 'ethics committee shopping'.

The Kenya experience may be useful in developing capacity of ERC members in other developing countries.

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