

## A review of a South African Research Ethics Committee

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The aim of this first review of the Research Ethics Committee at the Nelson R Mandela School of Medicine, KwaZulu-Natal, South Africa, is to provide insight into its structure, composition, procedures and workload, and to assess its strengths and weaknesses.

The Nelson R Mandela School of Medicine, University of Natal, is the only medical school in the province of KwaZulu-Natal, which has a population of 10.5 million. For more than two decades after its inception in 1950, it was the only tertiary institution in South Africa providing medical training for black (African, Indian and Coloured) students.

KwaZulu-Natal is the epicentre of the HIV/AIDS pandemic. The antenatal prevalence of HIV was 32.5% in 1999. Other prevalent diseases are tuberculosis, malaria, malnutrition and several malignancies such as that of the cervix and the oesophagus. Health care in South Africa is provided by both the private and public sector. People using the private sector generally have access to privately funded medical aid schemes, and tend to have disease patterns resembling those found in the western world. The public sector is utilised by the majority of the population with a wide spectrum of disease including those seen in developing countries. Thus researchers in South Africa have a unique opportunity to investigate diseases of both developed countries and the developing world.

In 1974 the Faculty of Medicine established an Ethical and Standards Sub-Committee. Its functions were: to review all research projects to ensure that they do not conflict with ethical principles on research involving human beings; to review at any time matters involving the care of patients in associated hospitals; to review from time to time the instructions given to students on ethics of medical practice, and to obtain, from the Medical Council, reports on any transgressions by its graduates.

Over the years a dedicated committee managed the faculty's research and ethical matters. More recently the job was entrusted to the Ethics sub-committee of the Post-graduate Committee. In view of a growing workload, it was decided to separate the Ethics sub-committee from the Post-graduate Committee. In 2000, the ethics committee was renamed the Research Ethics Committee (REC) and currently serves to provide an ethical review of research by the staff and students at the university, and also by other researchers within the province of KwaZulu-Natal.

### Methods and findings

A retrospective analysis of all applications submitted to the REC during the years 1997 to 1999 was undertaken. Demographic details of the committee members were obtained anonymously from the human resource office. The

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REC granted ethical approval for the study.

**Composition** The REC is composed of 23 members, 15 of whom were elected and 5 co-opted. A registrar representative also serves on the committee. The Dean and Deputy Registrar of the Faculty of Medicine at the University of Natal are *ex-officio* members. Seventeen of the 23 members were male. As for a racial breakdown, 12 of the members were Indian, 9 white and 2 were African. No African females serve on the committee. The average age of the members of the REC is 50 with a range of 26-66 years. An administrative officer and a committee clerk assist in management of the committee.

Members of the REC are from the administration and various branches of medicine, as well as the social sciences. Only two are in private practice; the rest range in seniority from professor to lecturer.

**Functioning** Monthly meetings are scheduled in advance and minutes of the meetings are taken. Quorum requirements are 50% of elected members. All members receive an agenda, and 16 members review protocols. These comments are referred to the chairman or vice-chairman who reviews and summarises them before sending them to the investigator to respond within a month. The amended protocol together with the original is then returned to the original reviewer for final approval or comment. All approved protocols are signed by the Dean, and submitted to a full sitting of the REC for ratification. At the meeting the submitted protocols may be ratified, rejected or approved conditional to modifications as recommended by the REC. An expedited review process is also available for protocols where ethical approval is required for funding purposes. These protocols are sent to three senior members of the REC for comment/approval.

**Workload** The committee reviewed 200, 168 and 170 protocols during 1997, 1998 and 1999 respectively. The number of studies that were closed, cancelled or withdrawn were 24, 17 and 20, respectively. Only one study was not approved during the three-year period; the use of a placebo arm in symptomatic patients was deemed to be unethical in this study as proven effective therapy was available for use in the control group. The average turnaround time for processing a research protocol was 96 days.

Protocols received by the REC included all studies on human subjects. These fall into four main categories: retrospective studies, faculty-sponsored research, sponsored trials and studies for higher degrees. More than 90% of protocols submitted for the first time were sent back for amendments or additional information. Reasons for this include: the patient information sheet had either inadequate information or was not written in lay-terms; the protocols contained contradictory information; for example there were conflicting age groups within the protocol; consent of the head of department and signatures of all stated role-players were not attached; there were 'statistical problems' such as inadequate sample size, ill-defined exclusion and

inclusion criteria, or the hypothesis or aims of study were poorly formulated

Research involving 'vulnerable groups' such as prisoners, children, psychiatric patients and patients in intensive care units raised most discussions and lengthy back and forth exchanges between the REC and researchers.

From 1997 to 1999, 43 (of 200 altogether that year), 31 (168) and 40 (170) respectively of all protocols submitted for review, formed part of submissions for higher degrees.

**Finances** The salaries of the administrative officer and committee clerk as well as other incidental expenses such as communication, photocopying and other operating expenses is borne by the University of Natal. The REC members are not paid for their services. For sponsored drug trials a one-off fee of R2500 (approximately US\$ 350) for processing the protocol (irrespective of outcome) is charged. Trials sponsored by pharmaceutical companies numbered 50, 43 and 52 for the period 1997 to 1999, respectively. This income was utilised for equipment and furniture for the REC office as well as upgrading computer network facilities for post-graduate students.

## Discussion

A number of interesting features arose in this review. The composition of the REC is not representative of the demography of the region. Less than 10% of the committee members are African, with no African females currently serving on the committee. Furthermore, the absence of a statistician/epidemiologist, and of representatives from consumer groups and faith-based organisations is a weakness. To this end we have initiated a programme to recruit members from the above groups.

The second major problem area regarding the REC is related to monitoring of research. Active monitoring is currently not undertaken by the REC, and this may lead researchers to become complacent about informed consent, appropriate documentation and adhering to the tenets of good research ethics. To address this problem the REC plans to initiate an audit process, which would randomly look at 10% of the studies undertaken. At present, researchers are required to supply the REC with bi-annual progress reports, but this feedback is not monitored and depends on the integrity of the researcher. Mechanisms to deal with conflicts between mentor and trainee researcher are currently not in place and the REC only becomes involved with the dispute if a written complaint is received.

The validity of informed consent is of grave concern to ethicists, especially in the multi-cultural context of South Africa. There is a subjective impression that researchers lack gender, cultural and religious sensitivities, which may lead to human rights abuse and/or coercion of patients to participate in studies. The free participation of subjects is also in dispute when it comes to therapeutic trials involving treatment not offered by the public health system. A good example of this is participation in anti-retroviral trials by HIV-positive patients who know that they would receive little or no treatment in state hospitals as opposed to a chance of receiving a placebo or trial drug. In addition the clinical monitoring of drug trial participants is at a much higher

level than the "usual standard of care" in state hospitals. In therapeutic trials, the principal researcher is paid according to the number of patients enrolled, which may lead to fiscally-driven recruitment.

A frequent criticism of the REC is the long delay between submission of protocols and final approval. There are several reasons for this, including: the poor quality of protocols submitted; investigators' delays in responding to queries, and inappropriate responses to queries; delays in obtaining translation of the patient information into Zulu by the investigators; and delays in obtaining replies from REC members

One possible justification for the long turnaround time is the onerous workload on REC members, which discourages people from serving on the REC. It is difficult to attract persons to take on the task of chairpersonship of the REC. Institutions serious about research should place more resources in the REC, and also consider remunerating its members.

Currently committee members are not required to have formal training in bioethics. The first Research Ethics Workshop was held in 2000, providing training for 16 participants. Partial sponsorship from the private sector helped defray the cost of course notes and reference materials for participants. It is expected that this workshop will become an annual event. It is anticipated that basic knowledge of research ethics will become a mandatory requirement not only for REC members but also for researchers involved with human subjects. The educational function of the REC should include training in bioethics for undergraduates and post-graduate students in a wide area of ethics including the management of HIV patients, end-of-life decisions, and informed consent. The REC can play a major role in continuing medical education in the field of bioethics and medical law.

## Conclusion

The REC at the Nelson R Mandela School of Medicine at the University of Natal provides an important service to both the community and researchers. However, to maintain its standards in the light of an increasing workload and more stringent regulatory and legal requirements, the REC must adopt a more professional business approach, and appoint a director as well as extra staff members to streamline its functioning and enable it to audit some of the research it approves. Perceiving the REC as a toothless, rubber-stamping bureaucratic burden will doom our faculty to mediocrity and cut-off the research funding vital to maintain our research and teaching status.

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