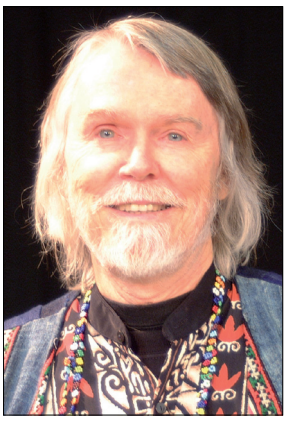
Editorial

What is the function of research ethics committees (RECs)?



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Carol Levine stated in 1988 that ethics in research was '… born in scandal and reared in protectionism'.[1] To answer the question 'What is the function of RECs?', it would be necessary to understand the notion of ethics in research from the perspective of past tragedies. There are many examples of studies in the health context where vulnerabilities of research participants have been exploited. Violations of participants' rights and dignities have in many instances resulted in morbidity and mortality, costing them their health and even their lives.

At the end of the World War II the Nuremberg trials exposed the terrible excesses of Nazi medical research on concentration camp prisoners. As a reaction, in 1947 two American doctors, Andrew Ivy and Leo Alexander, together with unnamed prosecutors in the Nuremberg Trials legal team, drew up a code of conduct called the Nuremberg Code.[2] Summarised, the 10 points of the Code add up to the need for voluntary consent before people participate in medical research, that such people may withdraw from the research at any time, and that there should be potential benefit and minimal harm to them as a result of their involvement.[3]

Several years later this was followed by a research code of the World Medical Association that evolved into the Helsinki Declaration of 1964. This Declaration is the core of clinical research and has been revised several times. Currently the 2008 revision is in force. The Declaration, which is an expansion of the Nuremberg Code, makes it clear that a physician's primary duty is to the patient under his or her care.[4]

Later, Henry K Beecher wrote in the *New England Journal of Medicine*[5] in 1966 of his concern for the rights of patients involved in medical research and described, anonymously, 22 experiments that he held were unethical because effective treatment was withheld; treatment was continued in the presence of side-effects; known harmful treatment was given to study the mechanism of side-effects; and procedures were done without the patient's consent. Beecher recommended that organisations undertaking medical research should set up committees to examine proposed research for the protection of participants. From his article grew the present-day research ethics committee system that screens research.

The regulatory and ethical framework for health research in South Africa

South Africa, as a country of immense research potential and increasing research activity, has also developed a regulatory and ethical framework for the protection of those who participate in research. It is important to bear in mind that South Africa is also a country of vast differences in health, education and income among its citizens. For this reason, many people may be at risk of exploitation in research without proper protection.

Research ethics committees in this country operate according to published guidelines from the National Department of Health.[6] The National Health Act[7] makes prior review and approval of health research by an REC compulsory. The National Health Act also requires that research is conducted in accordance with the protections of rights and dignity of participants as espoused in the South African Constitution.[8]

Definition of health research

'Health research' is defined in the National Health Act as including any research that contributes to the knowledge of:

- the biological, clinical, psychological or social processes in human beings
- improved methods for the provision of health services
- human pathology
- the causes of diseases
- the effects of the environment on the human body
- the development or new application of pharmaceuticals, medicines and related substances
- the development of new applications of health technology.

This definition of health research is quite broad, and most research will therefore require review by a research ethics committee. Research itself is defined as the systematic search or enquiry for knowledge. It is important that results of research, especially where they could have an impact on society, are published and shared with others. Studies could include projects designed to understand normal or abnormal physiological or psychological functions and social phenomena. Clinical research also includes studies that evaluate diagnostic, therapeutic or preventive interventions and variations in services or practices. Research activities may include invasive or non-invasive procedures. Some examples are surgical interventions, removal of body tissues or fluids, administration of chemical substances or forms of energy, dietary modifications, daily routine or service delivery, alteration of the environment, observation, administration of questions or tests and review of records.[6]

Editorial

Using the principles during ethics review

Respect for persons. RECs pay great attention to the process of consent for enrolment into an investigation. This consent must be voluntary and informed, should preferably be written, and needs to be gained before enrolment in a study except in certain situations such as critically ill people. Informed consent means that a participant in a study must understand what is proposed. This is frequently a problem because of language difficulties and low literacy levels. Cultural factors may also play a role. There are many vulnerable groups for whom special care must be taken, for example those with physical or mental reasons for incompetence to consent, prisoners, soldiers, subordinates to a researcher, minors, orphans, and the critically ill.

Non-maleficence/beneficence. Ensuring that the science is of a high standard is important in ensuring that research participants are protected against physical harms. Harms could also be of a psychological, social or economic nature. Some research could probe sensitive issues and result in re-traumatisation or trigger off psychological reactions. Stigma to individuals or cohorts of participants could result because of social harms.

Justice.[9] There is an ethical obligation to treat each person in accordance with what is right and proper. In research the justice principle is primarily that of distributive justice. There should be equitable distribution of both burdens and benefits of research participation. The study should leave the participant and or community better off or no worse off. Researchers have an obligation to justify their choice of research questions and to ensure that such questions are neither gratuitous nor result in the exploitation of study participants. The selection, recruitment, exclusion and inclusion of research participants must be just and fair and based on sound scientific and ethical principles. Where research involves participants from vulnerable communities, added protections will be necessary to safeguard their vulnerabilities. There needs to be justification for doing research in vulnerable communities. Moreover, the research should be responsive to their particular vulnerabilities.[9]

Conclusion

It can be seen that an effective system of review of the ethical propriety of research is a crucial safeguard for protecting the vulnerable and innocent from harm. The function of RECs is to facilitate ethical research and not to impede research, and there are strict regulatory guidelines that govern the research process.

So why has the *SAJBL* published a paper in this issue that did not receive final ethics clearance from its institutional REC? The paper in question is entitled 'Ethical dilemmas and financial burdens faced by clinical dental students in a "quota-driven" curriculum', by Sykes *et al*. The ethical dilemmas in respect of the review are described by the researchers in the manuscript. The research exposes deception and fraudulent and unethical practice by both senior students and laboratory technicians in a health sciences faculty. After extensive consultation with relevant experts, and bearing in mind that the function of ethics review is to protect the innocent and not the corrupt, an editorial decision was taken to proceed with publication. It is hoped that the publication of this article will create awareness among academics and educators of the existence of unprofessional behaviour among students, and stimulate discussion and debate not only on REC functioning but also on how problems of deception and lack of professionalism are to be handled when exposed in research.

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