

PREAMBLE

Progress in science has resulted in the development of innovative medical treatments, many of which could be beneficial to people living in low-income countries.

In recent years, South Africa has become a sought-after venue for conducting health research that could lead to the development of some of these innovative new medical treatments. The scientists who conduct the research are bound by the requirements of evidence-based medicine. Nevertheless, in the course of the work that is done, the human rights of poor and marginalized people and those who do not understand the processes of research are frequently violated. This is of grave concern to the South African government, which seeks to uphold the human dignity of all of its citizens and to protect their human rights. In particular, we must provide adequate protection for people who are especially vulnerable as a result of poverty or who might currently be underserved.

Research ethics are bound by various national and international codes and guidelines, supplemented by the *Universal Declaration of Human Rights (1948)*. In terms of these documents, all research involving human subjects should be conducted in accordance with four basic ethical principles, namely: respect for human beings; beneficence, non-maleficence; and justice.

These guidelines, entitled "*Ethics in Health Research: Principles, Structures and Processes*" contain our national policy on the ethical practice of research, in accordance with our specific national needs. They establish mechanisms for the ethical review of studies conducted on human subjects, and draw attention to the need to consider the ethical implications of professional action. In this way we are endeavouring to inculcate high professional standards in regard to both human attitudes and quality of research.

These guidelines are intended for use by investigators, ethical review committees, administrators, health-care practitioners, policy-makers, and community representatives. Ethics Committees should be especially vigilant when considering research proposals involving vulnerable populations like children, pregnant and nursing women, persons with mental illnesses or handicaps, members of communities unfamiliar with medical concepts, and persons with restricted freedom, such as prisoners. Similar vigilance should be applied to proposals for invasive research that has no direct benefit for its subjects.

The writers of these guidelines wanted to incorporate into them some reference to the work of traditional health practitioners, since this is the one of the latest branches of healing to be given official recognition in South Africa. However, this proved to be impossible as a result of the paucity of available information. Hopefully, with the strengthening of intellectual property rights in South Africa, more information will become available in this significant area, and considerations

regarding research related to traditional medicine can, in future, be incorporated into an updated version of these guidelines.

I wish to thank all of those who participated both formally and informally in the writing of these guidelines. Your work will greatly enhance the dignity of South African citizens.

A handwritten signature in black ink, appearing to read 'M. Tshabalala', written in a cursive style.

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ACKNOWLEDGEMENTS

The guidelines on Ethics in Health Research: Principles, Structures and Processes has been developed to ensure that research conducted in South Africa adds value to the country and promotes protection of human participants in health research. These guidelines have therefore been developed to protect the rights of individual research participants. Internationally accepted standards and the following were considered.

- There should be an increasing focus on research relevant to the needs of vulnerable populations. Exploitation of participants, or their use as mere means to the ends of others, should be explicitly excluded by ensuring that the research is of relevance to the individuals participating in the research as well as to their communities.
- The potential benefits of research should considerably outweigh potential risks or harms to vulnerable individuals and communities.
- Research participants should be encouraged to participate in planning and conducting studies.
- Research in developing countries should be linked with capacity building in health care, and with economic and educational empowerment that has beneficial effects on the delivery of health care and on progress generally in the host country.
- The results of research should have the potential to produce long-term benefit for communities who participate in research.
- The National Health Research Council in due course will modify and adapt these guidelines as required.

The Department is grateful to the Directorate: Health Systems Research, Research Coordination and Epidemiology for the development of these guidelines. The Chairperson of the Interim National Health Research Ethics Committee Prof. Solomon Benatar and his team is also acknowledged for the expert and technical input into and finalisation of these guidelines.

These guidelines serve as a technical reference to all research institutions and organisations involved in research on human participants, and it is hoped that they will be used in the context of protecting all humans participating in such research.



**ACTING DIRECTOR-GENERAL
DEPARTMENT OF HEALTH**