

## 1. THE IMPORTANCE OF ETHICS

### 1.1 Introduction

South Africa is undergoing transformation into a non-racial, non-sexist, democratic state in which human dignity, equality and the advancement of human rights are respected, promoted and protected under the South African Constitution Act, 1996 (Act No.108 of 1996). In particular, section 12(2) of the Bill of Rights provides that ‘Everyone has the bodily and psychological integrity, which includes the right (b) to security in and control over their body; and (c) not to be subjected to medical or scientific experiments without their informed consent.’

South Africa provides a unique and highly attractive research environment, with its mix of developed-country skills, expertise and infrastructure and its developing-country burden of disease. This environment has attracted many researchers. The clinical trial industry in South Africa reportedly increased by 40% between 1997 and 1998 (Christley, 1998) and yielded an estimated total budget of R826 million during 2000 (Joffe, 2000).

Increasing research activity, competition in research and the attractive research environment may sometimes result in dishonest and fraudulent practice. The need for a broad statement on ethics and health research in South Africa is therefore urgent.

### 1.2 Key Texts

Much work has been done internationally to develop guidelines for the conduct of health research in human participants. Key texts, which should be essential reading and reference sources for South African-based researchers, are listed in Appendix A with some additional references of interest.

### 1.3 Scope of the Guidelines

The term ‘research’ covers a broad range of activities and can be defined as, ‘the systematic search or inquiry for knowledge’ (Katzenellenbogen, Gear & Tollman 1997). A more detailed understanding of health research and of a research project may be obtained from the description provided by the US National Commission for the Protection of Human Subjects:

*‘A research project generally is described in a protocol that sets forth explicit objectives and formal procedures designed to reach those objectives. The protocol may include therapeutic and other activities intended to benefit the subjects, as well as procedures to evaluate such activities. Research objectives range from understanding normal and abnormal physiological or psychological functions or social phenomena, to evaluating diagnostic, therapeutic or preventive interventions and variations in services or practices. The activities or procedures involved in research may be invasive or non-invasive and include surgical interventions; removal of body tissues or fluids; administration of chemical substances or forms of energy; modifications of diet; daily routine or service delivery; alteration of environment; observation; administration of questions or tests; randomisation; review of records etc.’*

For the purposes of this document, the above statement should be used to guide the reader’s understanding of health research.

### 1.4 Ethics and Research

To be ethical, all health research on animals and on human participants must be scientifically sound. Ethics are as important as scientific considerations when reviewing a research project. A South African-based ethics committee must review the ethical and scientific rigor of all research projects to

be conducted in South Africa. More information on the process of ethical approval in South Africa may be found in Section 2 of this document.

### **1.5 Ethics and Legislation**

In due course, South African ethics committees will receive guidance from the National Health Research Ethics Council. The role of the Council will be to promote and monitor compliance of South African ethics committees within relevant legislation and regulations, ethical guidelines and standards. The National Health Research Ethics Council is to be established in terms of the National Health Act, 2003 (Act No. 61 of 2003).

### **1.6 Applicability of these Guidelines**

The principles outlined in this document should guide all research involving animals and human participants in any discipline relating to health. South African ethics committees are encouraged to adopt these principles to guide their efforts in assessing all health research projects.

All health research in South Africa, including research undertaken by military and other national bodies, should be subject to these Guidelines. Those who conduct 'secret' research involving human participants should be held to the same levels of accountability.

Compliance with these standards and with other national and international scripts reassures the public that the rights, safety and well being of study participants are protected.

### **1.7 Research and Animals**

The researcher should assure an Animal Ethics Committee that the study will be conducted in compliance with policies and standards required for performing research on animals. Under the provision of the South African Medical Research Council Act, No 58 of 1991, the Medical Research Council (MRC) is compiling guidelines: Use of Animals in Research (Book 3). Guidelines concerning animals in biomedical research are also available in the 'National Code for Animal Use in Research, Education, Diagnosis and Testing of Drugs and Related Substances in South Africa' published by the Director General of Agriculture.