health

Department:
Health
REPUBLIC OF SOUTH AFRICA

POLICY FRAMEWORK FOR ETHICS APPROVAL AND ENDORSEMENT OF HEALTH RESEARCH BY NATIONAL DEPARTMENT OF HEALTH

1. Introduction

The importance and benefits of health research is recognized and acknowledged in South Africa. Hence important health research, medical or scientific experimentation requirements are included in the South African legislative documents such as section 12(2) (c) of the South African Constitution; (Act No. 108 of 1996), National Health Act (NHA) (Act No. 61 of 2003; Ethics in Health Research: Principles, Structures and Processes (2004); and Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa (2006). The fundamental requirements to approve and endorse health research by the Department of Health are embedded in these documents.

2. Purpose

The purpose of this document is to consolidate procedures drawn from different sources into a single document to approve and endorse health research by the Department. The intention is to standardize approval and endorsement of health research using a single reference document.

3. Definitions

3.1 According to the NHA of 2003, Health Research includes any research which contributes to knowledge of-

(a) the biological, clinical, psychological or social processes in human beings;

(b) improved methods for the provision of health services;

(c) human pathology; causes of the disease;

(d) the effects of the environment on the human body;

(e) the development or new application of pharmaceuticals, medicines; and

(f) the development of new applications of health technology.

3.2 "Health Research Ethics Committee" means any committee registered in terms of section 73.

3.3 Clinical trials refers to any investigation involving human participants (including patients and other volunteers) intended to discover or verify the clinical, pharmacological and/or other pharmacodynemic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining their safety and/or efficacy (Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa).

4. Approval process of health research by the Department of Health

All research taking place in South Africa should meet the requirements in the following legislative documents: Chapter 9 of the NHA No.61 of 2003; Chapter 3 of the Ethics in Health Research: Principles, Structures and Processes (2004); and Chapter 2 of the Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa (GCP) (2006).

The researcher should also ensure that the research protocol is submitted to the health Research Ethics Committee (REC). According to section 1.6 of the GCP,

all clinical trials must apply to the Medicines Control Council (MCC) for approval and must register on the South African Clinical Trials register (SACTR) before the study commences.

4.1 Research to be conducted on human participants must conform to the requirements of sections 71(1) and 73(2) of the NHA. According to section 71(1) of the NHA the following requirements should be satisfied: Notwithstanding anything to the contrary in any other law, research or experimentation on a living person may only be conducted-

(a) in the prescribed manner; and

(b) with the written consent of the person after he or she has been informed of the objects of the research or experimentation and any possible positive or negative consequences of his or her health.

4.2. Based on section 3.4 of Ethics in Health Research: Principles, Structures and Processes (2004), all research protocols involving human participants must be submitted to an REC registered with the National Health Research Ethics Council (NHREC).

5. Endorsement process of health research by the Department of Health

5.1. Research documents to be submitted for endorsement by the Department include the following:

(a) Research protocol.

(b) Approval letter from an REC registered with National Health Research Ethics Council (NHREC).

(c) Approval letter from the institution conducting research.

(d) In case of Clinical Trials, the following additional documents are required:

i. Medicines Control Council approval letter; and

ii. Registration number from the South African Clinical Trial Register (SACTR).

5.2 Endorsement

(a) Endorsement of research by the Department of Health will be based on the required documents in section 4 above.

(b) The researcher must submit documents in section 4 of this document when requesting endorsement from the Department.

(c) The researcher must ensure the research study requesting endorsement is relevant to the DoH strategic focus and or priorities.

Approved by:
DR. A MOTSOALEDI, MP
MINISTER: HEALTH
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