No. R. 135 23 February 2007

NATIONAL HEALTH ACT, 2003

REGULATIONS RELATING TO RESEARCH ON HUMAN SUBJECTS

The Minister of Health intends, in terms of section 90 of the National Health Act, 2003 (Act No. 61 of 2003), to make the regulations in the schedule.

Interested persons are invited to submit written comments on the proposed regulations, or any representations they may wish to make in regard thereto, to the Director-General: Health, Private Bag X828, Pretoria, 0001 (for the attention of the Director: Health Systems Research within two months from the date of publication of this notice.

SCHEDULE

Definitions

1. In these regulations, "the Act" means the National Health Act, 2003 (Act no. 61 of 2003), and any word or expression to which a meaning has been assigned in that Act, shall have that meaning and unless the context indicates otherwise:

"artificial insemination" means the placing of male gametes (sperm) into the female reproductive tract by means other than copulation;

"Council" means the National Health Research Ethics Council established under section 72 of the Act;

"genetic research" means research on genetic material;

"research ethics committee" means a committee contemplated in section 73 of the Act;

"Medicines Control Council" means the Medicines Control Council established in terms of section 2 of the Medicines and Related Substance Act, 1965 **(Act** No. 101 of 1965);

"minimal risk" means the probability or magnitude of harm or discomfort anticipated in the research is not greater in itself than that ordinarily encountered in daily life;

"non-therapeutic research" means any research not directed towards the benefit of the individual but rather towards improving scientific knowledge or technical application;

"stem cell" means any embryonic stem cell, circulating progenitor cell, bone marrow progenitor cell, umbilical cord progenitor cell, haemopoietic progenitor cell or any cell that is capable of replacing (proliferating) and giving rise to a differentiated cell; and

"vulnerable persons" means those whose willingness to volunteer in a research study may be unduly influenced by the expectation of benefits associated with participation.

CHAPTER 1

Principles on health research

2. Any form of health research conducted in South Africa, which involves the participation of human subjects must:

(a) be relevant both to the overall health and developmental needs of the people of the Republic and the individual needs of those who suffer from the disease and or concerns of the study;

(b) have a valid scientific methodology and a high probability of providing answers for the specific research questions that are posed;

(c) be managed and conducted by a suitably qualified principal investigator who has extensive experience in the field of health research, who is also a resident of South Africa:

(d) ensure that research participants are well informed to make informed choices;

(e) ensure that participants' rights to privacy and confidentiality are protected;

(f) ensure that selection, recruitment and inclusion/exclusion of research participants in a research project are just and fair;

(g) be preceded by a risk-benefit analysis;

(h) must undergo independent review by an accredited registered health research ethics committee; and

(i) clinical research, must be registered on the South African National Clinical Trials Register.

Obligations of researchers

3. (1) **A** researcher conducting research involving human subjects is obliged to:

(a) adhere to the requirements as stated in regulation **2;**

(b) submit their research proposals for approval to an accredited Research Ethics

Committee and where necessary, to the Medicines Control Council or the Council;

(c) disseminate research results, whether negative or positive, in a timely and competent manner;

(d) disclose the sources and extent of funding for the research to participants and Research Ethics Committee;

(e) ensure monitoring of safety on research activities; and

(f) refer participants for professional assistance where necessary.

Participation of special classes of people in research studies.

4. (1) Children can only participate in research in instances where:

(a) the research poses a minimal risk to the child;

(a) the research poses a greater risk, but possibly be for the benefit of the child;

(b) the research can only be done on children; and

(c) the parent or legal guardian of the child gives consent for such a child to participate. Always, refusal to participate by a child should precede the consent of the parent/legal guardian.

(2) Research on persons with intellectual or mental impairment must:

(a) strictly involve mental disability, so that it is necessary to involve persons who are mentally disabled;

(b) be sufficiently justified for involving, as the study population, persons with mental disabilities who are institutionalised;

(c) have suitable evaluation procedures to confirm that the participant is incapable of giving informed consent;

(d) ensure that the consent by the person responsible for the participant is free from coercion; and

(e) ensure that no or minimal risk is involved, and if minimal risk is involved, that it should be outweighed by the anticipated benefits to the participants.

(3) In approving proposals for research, special attention should be given to the vulnerability of persons who are in dependent relationships or comparable situations like:

(a) older persons and their care-givers:

(b) patients and health care professionals;

(c) students and teachers;

(d) persons with life-threatening diseases; and

(e) prisoners and the relevant prison authorities.

(4) In approving proposals for research, extra attention should be given to research that involves the participation of women and in particular-

(a) exclusion of women in research studies should be scientifically justified;

(b) no research activities involving pregnant women and foetuses may be undertaken unless:

(i) appropriate studies on animals and non-pregnant individuals have been completed;

(ii) the purpose of the activity is to meet the health needs of the mother of that particular foetus; and

(iii) the risk to the foetus is minimal, and in all cases, is the least possible risk for achieving the objectives of that activity.

Other types of research that need additional consideration.

5. (1) Participants involved in indigenous medical systems research must be subject to the same degree of respect **and** protection from harm as participants in scientific medical research.

(2) Research into emergency medical treatment must involve participants who are experiencing medical emergencies, while bearing in mind that it is not always possible to obtain informed consent from such a group. **All** such research should receive prior approval by a research ethics committee

(3) Appropriate provision must be made for long-term care and observation of participants who take part in an innovative therapy or intervention.

(4) Research studies involving prisoners must:

(a) be registered with the Council;

(b) present only a minimal risk and minimal inconvenience to the participants;

(c) be preceded by expert consultations; and

(d) ensure protection of the dignity and humanity of the prisoners.

(5) Research on vulnerable persons must be evaluated with caution, to ensure that:

(a) persons in those communities would not ordinarily be involved in research that could be carried out in non-vulnerable communities; and

(b) the research is responsive to the health needs and the priorities of the community in which it is carried out.

Informed Consent

6. Persons on whom research is to be conducted have the right to be informed of:-

(a) the purpose of the research;

(b) treatments and possibility of random assignment of each treatment, if the research involves treatment;

(c) methods and procedures to be followed or used during the research;

(d) alternatives apart from participating in a research;

(e) potential or real harm and risks involved in participation;

(f) expected benefits to the participant and other persons in the research;

(g) extent to which confidentiality and privacy will be maintained;

(h) available insurance in the event of injury or damage caused whilst participating in research;

(i) details of the contact person in the event of a research related injury;

(j) incentives given for participation as well as any differences in incentives, if any;

(k) in cases of clinical trials. the availability of treatment beyond the duration of the trial;

(l) details of the sponsor and any potential conflict of interests; and

(m) proof of ethics committee approval.

CHAPTER 2

Genetic, Stem Cell Research and Reproductive Health

7. (1) Informed consent must be obtained from donor of precursor of the stem cells before conducting stem cell research or therapeutic cloning.

(2) Research findings and any therapeutic interventions emanating from stem cell research is not subject to intellectual property right.

(3) **A** person from whose body genetic material, stem cells, blastomeres, polar bodies, embryos, embryonic tissue or small tissue biopsies, has been removed or withdrawn may be reimbursed for any reasonable expenses incurred by him/her for such removal or withdrawal.

(4) Before artificial fertilisation can be performed on any person informed consent must be obtained from the donor of the gamete or embryo.

(5) **A** person from whose body a gamete or an embryo has been removed orwithdrawn
may be reimbursed for any reasonable expenses incurred by him/her for such removal or withdrawal.

(6) No person may, without the Minister's approval, import or export human biological material such as zygotes, embryos, gametes for artificial fertilisation or artificial insemination or DNA, RNA, cultured cells, stem cells, blastomeres, polar bodies, embryonic tissue and small tissue biopsies for genetic testing, research or therapeutics.

Review of Research Proposals by Health Research Ethics Committees

8. All health research studies involving human participants must:

(a) be reviewed by a Health Research Ethics Committee which is registered with the Council;

(b) satisfy the requirements as determined by such a Committee; and

c) adhere to the recommendations made by the Committee.

CHAPTER 3

Research involving animals

9. *Where animals are used for research that will benefit humans, the following must be*

adhered to:

(a) the research proposal must also be submitted to an animal research ethics committee; and

(b) the researchers must consult and comply with the regulations and guidelines prescribed by the National Department of Agriculture.

ME TSHABALALA-MSIMANG
MINISTER OF HEALTH