GOVERNMENT NOTICE

DEPARTMENT OF HEALTH

No. R. *7* ***5* January *2007***

Annexure A 1

NATIONAL' HEALTH ACT, 2003

REGULATIONS REGARDING THE USE OF HUMAN DNA, RNA, CULTURED CELLS, STEM CELLS, BLASTOMERES, POLAR BODIES, EMBRYOS, EMBRYONIC TISSUE AND SMALL TISSUE BIOPSIES FOR DIAGNOSTIC TESTING, HEALTH RESEARCH AND THERAPEUTICS

The Minister of Health intends, in terms of section 90(1), read with section 68(1) of the National Health Act 2003 (Act No. **61** of 2003), and after consultation with the National Health Council, to make the regulations in the Schedule.

Interested persons are invited to submit any substantiated comments or representations on the proposed regulations to the Director-General: Health, Private Bag X828, Pretoria, 0001 (for attention of Ms Lineo Motopi: Human Genetics), within three months of the date of publication of this notice.

SCHEDULE

Definitions

1. In this Schedule any word or expression to which a meaning has been assigned in the Act shall have such meaning and, unless the context otherwise indicates-

"autosomal" refers to one of the 22 pairs of chromosomes that are not sex chromosomes;
"biological material" is any material from a human being including blood, cells, tissues, DNA, RNA, polar bodies, blastomeres, embryos and gametes;
"blastocyst" is a pre-implantation embryo consisting of an outer layer, which forms the placenta and a 30-200-cell inner cell mass, which develops into the foetus;
"blastomere" also called a "blastocyte", means an undifferentiated embryonic cell, derived from a blastocyst;
"carrier" means an individual who has a disease-causing mutation but will not develop the condition. Most commonly used with regard to autosomal and X-linked recessive disorders and refers to the situation in which the individual has one normal and one false gene;
"cell?' means the basic structural and functional unit in people and all living things. Each cell is a small container of chemical and water wrapped in a membrane;
"central data bank" means an electronic data bank established by the Director General in terms of reglulation **7,** into which all information regarding human DNA, **RNA,** cultured cells, blastomeres including single cells from developing blastocysts, amniocytes, polar bodies, stem cells and small tissue biopsies donations are stored;
"chromosome" is a thread-like structure and made up of DNA found in the nucleus of all cells with the nuclei of human cells normally contain **46** chromosomes, arranged in 23 pairs;

"competent person" means -

(a) in the case of the intravenous withdrawal of blood, a person registered in terms of the Health Professions Act, 1974 (Act No. 56 of 1974) as a medical practitioner or the Nursing Act, 2005 (Act No. 33 of 2005) as a nurse, or in the case of intra-arterial withdrawal of blood, a medical practitioner registered as a specialist in the procedure;

(b) in the case of a finger prick for the withdrawal of a drop of blood for testing purposes, a person mentioned in paragraph (a) or any person who has been trained to perform such a procedure;

(c) in the case of a developing blastocyst, an expert in organisation and maintenance of a basic or clinical embryology laboratory as well as tissue culture techniques;

(d) in the case of a gamete removal or withdrawal, a gynaecologist with training in reproductive endocrinology, particularly in use of ovulation-inducing agents and the hormonal control of the menstrual cycle; or

(e) in the case of collection of cells from the inside of the cheek (buccal swab), any person who has been trained to perform such a procedure or the person himself/herself who provides the sample for genetic testing;

"cultured cells" are cells that have been grown outside the body;

"differentiation" is the process whereby an embryonic cell becomes specialised;

"DNA" is the abbreviation for deoxyribonucleic acid, which is a nucleic acid composed of building blocks called nucleotides;

"donation" means donation of human DNA, RNA, cultured cells, stem cells; blastomeres, polar bodies, embryos, embryonic tissue and small tissue biopsies for genetic testing, health research or therapeutic purposes,

"donor" means a person from whose body biological material has been removed/withdrawn, with informed consent, for the purpose of research, genetic testing or therapeutics;

"embryonictissue" means tissue from an embryo;

"embryonic stem cell" means any cell from the 30-200 inner cell mass of the blastocyst;

"export" means export from the South Africa by any means;

"foetus" means a human offspring from eight weeks after conception until birth;

"foetal tissue" means tissue from a foetus;

"import" means import into South Africa by any means;

"informed consent" means an agreement by which a participant, donor or health care user voluntarily confirms his or her willingness to participate in research, donation or treatment, after understanding all aspects of such research, donation or treatment that are relevant to his or her decision;

"in vitrofertifisation" is the process whereby an ovum (egg) is fertilised with a sperm outside the body, Embryos thus produced could be introduced into the womb of a woman for reproductive purposes or by permission; excess embryos may be used to derive embryonic stem cells;

"medical practitioner" means a person registered with the Health Professions Council of South Africa as such;

"medical scientist" " means a person registered as a medical scientist with the Health Professions Council of South Africa as such;

"mutation" means a permanent change and structural alteration in the DNA;

"polar body" refers to a product that is formed during the development of the female gamete (during meiosis), which contains little cytoplasm and a haploid number of chromosomes;

"prescribed institution" means an institution such as university, private laboratory or assisted reproductive facility, accredited by the South African Accreditation Systems (SANAS) to perform stem cell research and related technologies;

"primordial germ cells" are stem cells found in the gonad of a foetus capable of becoming ova or sperm;

"RNA (ribonucleic acid)" an abbreviation for ribonucleic acid, a nucleic acid molecule similar to DNA but containing ribose rather than deoxyribose;

"section" means a section of the Act;

"serious genetic condition" means a condition which compromises the functional, physical or mental ability of a person and which can sometimes be lethal;

"sex limited" is a trait that affects only one type of sex. (i.e. is present in only males or females);

"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 replicating (proliferating) and giving rise to a differentiated cell; and

"the Act" means the National Health Act, 2003 (Act No **61** of 2003);

CHAPTER 1

HARVESTING AND USE OF HUMAN DNA, RNA, CULTURED CELLS, STEM CELLS, BLASTOMERES, POLAR BODIES, EMBRYOS, EMBRYONIC TISSUE AND SMALL TISSUE BIOPSIES FOR DIAGNOSTIC GENETIC TESTING, HEALTH RESEARCH AND THERAPEUTICS

Harvesting of human biological material

2. *(a)* No person, except a registered medical practitioner or dentist, may harvest biological material for genetic testing, health research or therapeutic purposes.

(b) Biological material for genetic testing, health research or therapeutic purposes may only be harvested in -

(i) a hospital or an authorised institution;

(ii) prescribed institution; or

(iii) for ancestry analysis, a research institution such as a museum.

Removal or withdrawal of biological material from living persons

3. (1) A person may not remove any biological material from the body of another living person for the purpose of genetic testing, health research or therapeutics, unless it is done -

(a) with the informed consent of the person from whom such biological material is removed; or

(b) where the person is younger that 18 years for the medical treatment of such person -

(i) an informed consent by a child over the age of 12 years, provided the child is of sufficient maturity and has the mental capacity to understand the benefits, risks, social and other implications of the procedure;

(ii) an informed consent of a parent, guardian or care giver where the child is younger than 12 years or the child is over 12 years but has no sufficient maturity or the mental capacity to understand the benefits, risks, social and other implications of the procedure;

(iii) consent by head of the health establishment in the case of an emergency;

(iv) consent by the Minister if the parent, guardian or caregiver of the child-

(aa) unreasonably refuses to give consent or assist the child in giving consent;

(bb) is incapable of giving consent or cannot assist the child in giving consent;

(cc) cannot be readily traceable; or

(dd) is deceased.

(c) where the removal or withdrawal is for the medial treatment of a person who is mentally ill as defined in section 1 of the Mental Health Act 2002, (Act No. 17 of 2002), -

(i) informed consent of the mentally ill, if he or she is capable of giving consent;
(ii) consent of a curator appointed by the court, a spouse, next of kin, a parent or guardian, major child, brother or sister, partner or associate if such mentally ill person is incapable of giving consent; and
(iii) consent by the head of the health establishment in the case of an emergency.

(2) No person shall carry out genetic research on archival material unless approved by a registered health research ethics committee referred to in section 73(1) of the Act.

Use of human DNA, RNA, cultured cells, blastomeres including single cells from developing blastocysts, amniocytes, polar bodies, stem cells and small tissue biopsies

4. DNA, RNA, cultured cells, amniocytes, stem cells, gametes, polar bodies, blastomeres and small tissue biopsies including single cells from developing blastocysts, may be removed or withdrawn from living persons and used for the following specific medical and dental purposes -

(a) DNA, RNA and chromosome-based genetic testing including:
(i) diagnostic tests;
(ii) testing for genetic carrier status;
(iii) antenatal diagnosis;
(iv) voluntary presymptomatic, predictive or susceptibility testing, screening tests, drug response or toxicity tests, identity or paternity testing;
(v) tests that are performed post-natally;
(vi) preimplantation DNA tests to be carried out on a polar body of an ovum, in order to ensure that an ovum that does not carry a mutation that causes a serious genetic condition can be selected for ***in vitro*** fertilisation;
(vii) preimplantation DNA tests following the removal of a polar body or one or two blastomeres of a developing embryo can be carried out for the purpose of ensuring implantation of an embryo, without a mutation that causes a serious genetic condition;

(b) Health research referred to in section 69(3) of the Act; or

(c) Studies of archeological, medical or heritage value on DNA obtained from human genetic material, conducted in terms of the of the National Heritage Resources Act, 1999 (Act No. 25 of 1999).

Preimplantation and prenatal testing for sex selection

5. Preimplantation and prenatal testing for selecting the sex of a child is prohibited except in the case of serious sex-linked or sex limited genetic conditions.

Removal of biological material from deceased persons

6. (1) Any organisation or institution or person that intends to use tissue from a deceased person for purposes of genetic testing, health research and therapeutics,

where no consent has been given by the deceased person before her or his death and where there is no evidence that the removal of the tissue or cells would be contrary to a direction given by the deceased before his or her death, must take steps contemplated in sub regulation **(2)** to locate the spouse, partner, major child, parent, guardian, major brother or major sister of a deceased person, in the specific order mentioned, in order to obtain consent.

(2) The steps must include, but not limited to, obtaining the name, address, the telephone number of the spouse, partner, major child, parent, legal guardian, major brother or major sister of the deceased person from:

(i) any person working in the relevant hospital, institution or facility where the deceased died;

(ii) any person who visited the deceased before his or her death or

(iii) any member of the South African Police Service who may be involved in investigating the cause of death of the deceased.

(3) In cases where none of the persons referred to in subregulation (2) can be located, an application, including evidence that the above steps have been taken must be submitted with the request to remove such tissue, to the Director-General in terms of section 62(3) of the Act.

Establishment of a Central Data Bank

7. The Director General will establish an electronic data bank into which all information regarding human DNA, RNA, cultured stem cells, stem cells, blastomeres, polar bodies, embryos, embryonic tissue and small tissue biopsies donations are stored.

CHAPTER 2

RESEARCH RELATING TO THE USE OF GAMETES, EMBRYOS, FOETUSES, CULTURED CELLS AND STEM CELLS.

Places where research on stem cells can take place

8. All authorised and prescribed institutions for research on stem cells should have as members of the team, a medical practitioner, medical scientist or medical technologist registered with the Health Professions Council of South Africa;

(a) in the case of the intravenous withdrawal of blood, a person registered in terms of the Health Professions Act, 1974 (Act No. 56 of 1974) as a medical practitioner or the Nursing Act, 2005 (Act No. 33 of 2005) as a nurse, or in the case of intra-arterial withdrawal of blood, a medical practitioner registered as a specialist in the procedure;

(b) in the case of a finger prick for the withdrawal of a drop of blood for testing purposes, a person mentioned in paragraph (a) or any person who has been trained to perform such a procedure;

(c) in the case of a developing blastocyst, an expert in organisation and maintenance of a basic or clinical embryology laboratory as well as tissue culture techniques;

(d) in the case of a gamete removal or withdrawal, a gynaecoiogist with training in reproductive endocrinology, particularly in the use of ovulation-inducing agents and the hormonal control of the menstrual cycle; and

(e) in the case of collection of cells from the inside of the cheek (buccal swab), any person trained to perform such a procedure or the person himself or herself who provides the sample for genetic testing.

Ownership of excess embryos, umbilical cord blood, abortedfoetuses before harvesting of stem cells

9. Ownership of-

(a) excess embryos from in vitro fertilisation, for the purpose of research, is vested with the donor;

(b) umbilical cord blood for the purpose of research, is vested with the donor;

(c) umbilical cord blood for the purpose of using the cord blood to harvest stem cells for the benefit of the child's or sibling's benefit in the future, is vested with the parents; and

(d) aborted foetuses for the purpose of research are vested with the donor.

Ownership of stem cells, after consent being given by donor to harvest stem cells

10. Ownership of stem cells derived from-

(a) excess embryos for the purpose of research, is vested with the State;

(b) umbilical cord blood for the purpose of research, is vested with the State;

(c) umbilical cord blood for the purpose of harvesting stem cells to use for the benefit of the child's or sibling's benefit in the future, is vested with the parents;

(d) aborted foetuses for the purpose of research is vested with the State; and

(e) other adult progenitor cells for the purpose of research are vested with the State.

Therapeutic cloning utilising adult,foetal and umbilical cord stem cells

11. Any competent person who wishes to utilise adult, foetal and umbilical cord stem cells, for therapeutic cloning must-

(a) apply for approval of the Minister, provided that such approval is supported by a recommendation of the National **Human** Genetics and Stem Cell Research and Ethics Subcommittee; a subcommittee of the National Health Research Ethics Council referred to in section 72 of the Act;

(b) undertake to document the research for record purposes;

(c) obtain informed consent from the donor of such stem cells; and

(d) ensure that the utilisation, if approved by the Minister, conforms to regulation 16.

Research utilising embryonic stem cells

12. Subject to regulation 16 excess embryos obtained from ***in vitro*** fertilisation may be used to derive embryonic stem cell lines for the purpose of research, provided there is -

(a) informed consent from embryo donor;

(b) approval from the Minister with recommendation of the National Human Genetic Stem Cell Research and Ethics subcommittee; and

(c) the applicant undertakes to document the research for record purposes.

Research utilisingprimordial germ cells

13. Subject to regulation 16, research on primordia1 germ cells obtained from aborted foetuses may be carried out -

(a) with prior informed consent from the donor of aborted foetus being obtained;

(b) with the approval of the Minister with recommendation of the National Human Genetics ad Stem Cells Research Ethics subcommittee; and

(c) if the applicant undertakes to document the research for record purposes.

Compensation in respect of withdrawal of blood, blastomeres, polar bodies, embryos, embryonic tissue and small tissue biopsies

14. **A** person from whose body blood, blastomeres, polar bodies, embryo, embryonic tissue or small tissue biopsies is removed, may only be reimbursed for reasonable expenses incurred by him or her in order to effect the donation concerned as referred to in section 60(2) of the Act.

CHAPTER 3

GENETIC, STEM CELL REGISTERS AND RESEARCH FINDINGS, WHICH INVOLVE THE LONGTERM STORAGE

Genetic material and Stem Cell Registers

15. (1) An authorised institution that performs genetic testing or that generates stem cells, must have separate registers to record such genetic testing or generation of embryonic stem cell lines.

(2) The authorised institution, must submit details of the registers referred to in sub-regulations (1) to the Director-General by the 31st March of each year.

(3) No person, except the National Human Genetics Stem Cell Research and Ethics Committee, shall have access to any information submitted to the Director General in terms of sub-regulation (2).

Researchfindings on stem cells

16. All stern cells and information derived from their research, together with any diagnostic, prophylactic or therapeutic substances emanating from this research shall not be subject to intellectual property rights. Intellectual property rights shall apply to all other forms of genetic research, as appropriate.

Storage and control of flow of Genetic information

17. All genetic medical records and other individually identifiable or related health information held or disclosed by an authorised institutions in any form, whether, electronically, orally or on paper should -

(a) be treated confidentially;

(b) ensure that health care providers or planners give patients a clear explanation of how they can use, keep and disclose their information;

(c) ensure that patients have access to their records;

(d) obtain patients' informed consent before information is released to health insurers, other health providers or any other relevant stakeholder as the need arises;

(e) ensure that the information is used for the specified purpose for which it was originally intended;

(f) obtain informed consent of patients or donors, to long term storage of genetic material, stem cells or research findings; **and**

(g) ensure that the records are destroyed after their purpose is completed.

Offences

18. Any institution, organisation that or person who contravenes these regulations or fails to comply with any provision of these regulations, is guilty of an offence, and liable upon conviction to a fine or imprisonment of not more than five years, or both such fine and such imprisonment.

MINISTER OF HEALTH