No. R. 263 **1 April 2011**

NATIONAL HEALTH ACT, 2003

REGULATIONS RELATING TO THE USE OF HUMAN BIOLOGICAL MATERIAL

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, within three months of the date of publication of this notice.

SCHEDULE

Definitions

1. In these Regulations 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 " means one of the 22 pairs of chromosomes that are not sex chromosomes;

"biological material" means material from a human being including DNA, RNA, blastomeres, polar bodies, cultured cells, embryos, gametes, progenitor cells and small tissue biopsies;

"blastocyst" means a pre-implantation embryo consisting of an outer layer, which forms the placenta and a 30-200-cell inner cell mass, which develops into a foetus;

"blastomere" also called a "blastocyte, means an undifferentiated embryonic cell derived from a blastocyst;

"cell" means the smallest structural and functional unit of an organism, consisting of cytoplasm and a nucleus enclosed in a membrane in living things;

"chromosome" **means** a thread-like structure made up of DNA found in the nucleus of all cells;

"competent person" means appropriately trained and qualified person and -

(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 a health professional trained as a phlebotomist;

(b) in the case of intra-arterial withdrawal of blood, a medical practitioner registered as a specialist in the procedure;

(c) in the case of a finger prick for the withdrawal of a drop of blood for testing purposes, a person referred to in the Regulations Relating to the Withdrawal of Blood From a Living Person for Testing;

(d) in the case of a developing blastocyst, a person trained in basic or clinical embryology as well as tissue culture techniques;

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

(f) in the case of sperm withdrawal, an expert in male reproductive health or an urologist;

(g) in the case of a foetal tissue, including amniocyte, chorionic villi and an utero cord blood, a medical practitioner registered as such under the Health Professions Act, 1974 (Act No. 56 of 1974); and

(h) in the case of research, a medical technologist or scientist registered as such under the Health Professions Act 1974, (Act No. 56 of 1974);

"Council" means the National Health Research Ethics Council referred to in section 72 of the Act;

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

"differentiation" means the process whereby stem cell becomes specialised;

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

"donation" means donation of human biological material for genetic testing, genetic training, genetic health research for therapeutic purposes;

"donor" means a person from whose body human biological material has been removed or withdrawn for the purpose of genetic testing, genetic training, genetic health research and therapeutics;

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

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

"in vitro fertilisation" means the process whereby a female gamete is fertilised with a male gamete outside the body of a female person;

"genetic carrier" means an individual who has a disease-causing mutation but will not develop the condition and the individual would have one normal and one faulty;

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

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

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

"progenitor cells" means cells which give rise to a distinct stem cell line;

"RNA" *means* ribonucleic acid molecule similar to DNA but containing ribose rather than deoxyribose;

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

"stem cell" means any cell that is capable of replicating (proliferating) and giving rise to a differentiated cell;

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

CHAPTER 1

REMOVAL AND USE OF HUMAN BIOLOGICAL MATERIAL FOR GENETIC TESTING, GENETIC TRAINING, GENETIC HEALTH RESEARCH AND THERAPEUTICS

Removal of human biological material

2. *(a)* No person, except a competent person, may remove biological material for genetic testing, genetic health research or therapeutic purposes.

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

(i) an authorised institution;

(ii) prescribed institution; and

(iii) a research institution prescribed in terms of the National Heritage Resources Act, 1999 (Act No. 25 of 1999), for ancestry analysis.

Removal or withdrawal of biological material from living persons

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

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

(b) where the person is younger than 18 years for the medical treatment of such person as defined in section 129 of the Children's Act, 2005 (Act No. 38 of 2005) -

(i) written 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 implications of the procedure;

(ii) written 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 and the mental capacity to understand the benefits, risks, social and implications of the procedure;

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

(iv) cconsent 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 treatment of a person with mental illness, written informed consent of-

(i) the mentally ill person, if he or she is capable of giving consent;

(ii) 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) the head of the health establishment in the case of an emergency.

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

Removal of biological material from deceased persons

4. (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 contemplated in subregulation (1) 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; or

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

(3) In cases where none of the persons referred to in sub-regulation (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.

Use of human biological material

5. Human biological material, may be removed or withdrawn from living persons for the following medical and dental purposes -

(a) DNA, RNA and chromosome-based genetic testing:

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

(c) Training referred to in section 64(1)(a) 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

6. 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.

CHAPTER 2

RESEARCH RELATING TO THE USE OF HUMAN BIOLOGICAL MATERIAL

Therapeutic cloning utilising adult, foetal or umbilical cord stem cells

7. 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;

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

(c) obtain written informed consent from the donor of such stem cells.

Research utilising embryonic stem cells

8. Excess embryos obtained from *in vitro* fertilisation may be used to produce embryonic stem cell lines for the purpose of research, provided that the competent person obtains-

(a) written informed consent from embryo donor;

(b) approval from the Minister; and

(c) an undertaking by the competent person to document the research for record purposes.

Research utilising primordial germ cells

9. Research on primordial germ cells obtained from aborted foetuses may be carried out provided that the competent person-

(a) obtains prior written informed consent from the donor of the aborted foetus;

(b) obtains the approval of the Minister; and

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

Compensation in respect of withdrawal of human biological material

10. A person from whose body human biological material was withdrawn may only be reimbursed for reasonable expenses incurred by him or her in order to effect the donation concerned as defined to in section 60(4) of the Act.

CHAPTER 3

HUMAN BIOLOGICAL MATERIAL REGISTERS

Human Biological Material Registers

11. (1) An authorised institution that performs genetic research or generates embryonic stem cells, must have separate registers to record such genetic research 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 Council by the end of March of each year.

(3) No person, except the Council, shall have access to any information submitted in terms of sub-regulation (2).

Storage and control of flow of genetic information

12. An authorised institution that keeps or discloses genetic material records and other individually identifiable or related health information in any form, whether electronically, orally or on paper must ensure that-

(a) the information is treated confidentially;

(b) health care providers or planners give users a clear explanation of how the user can use, keep and disclose their information;

(c) users have access to their records;

(d) user's written informed consent is obtained before information is released to health insurers, other health care providers or any other relevant person;

(e) the information is used for the purpose for which it was originally;

(f) the written informed consent of the user or donor is obtained for long term storage of genetic material, stem cells or research findings;

(g) the records are destroyed after the purpose for which they were created has been served; and

(h) the information is treated as anonymous if used for research purposes.

Offences

13. Any 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 10 years, or both such fine and such imprisonment.

DR A MOTSOALEDI
MINISTER OF HEALTH