NOTICE 320 OF 2008

DEPARTMENT OF HEALTH

NATIONAL HEALTH ACT, 2003 (Act 61 of 2003)

DRAFT REGULATIONS REGARDING THE GENERAL CONTROL OF HUMAN BODIES, TISSUE AND ORGANS FOR TRANSPLANTATION

The Minister of Health intends, in terms of section 68(1) 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 Cluster Manager: Non-Communicable Diseases), within three months of this notice.

SCHEDULE

CHAPTER 1

Definitions

1. In these regulations any expression to which a meaning has been assigned to in the Act shall bear that meaning and, unless the context indicates otherwise-

   "Act" means the National Health Act, 2003 (Act no 61 of 2003) and any regulations promulgated in terms of the Act.

CHAPTER 2

DONATION OF ORGANS OR TISSUE

Institutions or persons to which human bodies or tissue may be donated

2. A human body or specific tissue, may be donated to any of the following institutions or persons-

   (a) a registered hospital;

   (b) an university or University of Technology ;

   (c) authorized institutions; or

   (d) any person who requires therapy in which the tissue concerned can be used for therapeutic purposes.

3. Except in the case of tissue as contemplated in section 61 of the Act, a donation shall be of no force and effect if any other institution or person than that referred to in regulation 2 is nominated as recipient;

4. If a person has made conflicting donations of her or his body or any specific tissue or organ thereof, effect shall be given to the donation which was last made and which complies with the provisions of Section 62 of the Act, provided that if such a person had first donated her or his entire body to one recipient and thereafter donated any specific tissue thereof to another recipient, the donation of her or his entire body shall be deemed to be the donation.

Approval of organ transplant facilities

5. In order for a transplant unit to be given approval to operate, the following criteria should be met, over and above the requirement in terms of section 36 of the Act:

(a) A transplant unit must be headed by a transplant surgeon or physician or pediatrician with at least 2 years experience in transplant medicine.

(b) A transplant unit must have the capacity and commitment to undertake uninterrupted lifetime, long-term care including immunosuppressive therapy and monitoring of recipients and donors.

(c) A transplant unit must have multidisciplinary expertise or regular access to such expertise in order to provide optimum care for assessment, transplantation and follow up of organ donors and transplant recipients including the services of social workers or psychologists.

(d) Annual inspections of transplant units to ensure compliance with these regulations and the requirements of the Act must be carried out by the relevant inspectorate of the Health Establishments or, where the relevant Inspectorate of Health Establishment does not employ an Inspector of Anatomy, by a medical practitioner delegated for this purpose.

(e) Full clinical support services to ensure the health and well-being of both organ donors and transplant recipients must be available twenty four hours a day to transplant units.

Licensing of transplant units

6. The provisions of Section 36 of the Act are applicable to transplant units and no authorizations, permits or designations contemplated in the Act shall be granted in respect of transplant units, as the case may be where the relevant transplant unit does not have a valid certificate of need.

CHAPTER 3

DONATION OF ORGANS AND TISSUE BY LIVING PERSONS

Removal of organs and tissue from living persons (genetically related or unrelated) for transplantation

7.(1) A person may not remove tissue from the body of a living person for the purpose referred to in section 56 of the Act unless:

(a) An explanation in respect of the following have been given to the donor and the recipient of the relevant tissue:

(i) The cost, risks and benefits of each of the treatment options or proposed health interventions.

(ii) The informed consent of both the donor and the recipient must be obtained in accordance with the provisions of section 6, 7, and 8 of the Act.

(b) Written consent form (Annexure A) completed in duplicate and signed by the donor and recipient in the presence of the health care provider who is part of the transplant team, indicating that the procedure or proposed health intervention has been explained to the donor and recipient and authorizing the removal of the relevant tissue from the donor's body, has been obtained from the donor and is also signed by the health care provider who explained the procedure to the donor;

(c) The tissue donor and recipient comply with the clinical and psychological requirements for tissue donation and transplantation reflected in these regulations as Annexure B.

(d) It has been conclusively established by the hospital or authorised institution that the motive of the donor is not for profit and the donor and the recipient have provided written affirmation to this effect.

(e) The recipient has been informed of lifelong follow-up protocol.

(f) The donor has been informed that he or she may withdraw the donation at any time.

(2) No person may remove an organ or tissue from a living person for transplant into another person without the Minister's written approval, unless the person into whom the organ is to be transplanted is genetically related to the person from whom the organ is removed.

(a) For the purpose of this regulation, a person is genetically related to:

(i) His or her natural parents and children
(ii) His or her brother and sisters of whole or half blood
(iii) The brothers and sisters of the whole or half blood of either natural parents and,
(iv) The children of brothers and sisters of whole or half blood
(v) The natural children of his brothers and sisters of the whole or half blood or of the brothers and sisters of the whole or half blood of either of natural parents.

(b) No person shall in any particular case be treated as related in any of those ways unless adequate proof of the claimed relationship has been established by the authorized institution.

Procedure for application for Ministerial approval for local and foreign unrelated donors

8. For transplants between persons not contemplated in regulation 7(2) (a), the Minister may grant permission for the transplant, on receipt of a written application and documentation detailed in Annexure C of these regulations.

Use of organ and tissue removed from living persons

9. Tissue removed from living persons may only be used for medical, dental, therapeutic and diagnostic purposes.

Transplants relating to Non-South African Citizens as donors or recipients

10. A Non-South African donor or recipient may not undergo a transplant operation in a South African health establishment or health agency unless:

(a) Written approval by the Minister has been obtained on receipt of:

(i) The documents referred to in regulation 8.
(ii) An written undertaking from the referring health care provider confirming that post transplantation care sufficient to ensure the continued health and well-being of the donor and the recipient will be provided in their countries respective countries of residence.
(iii) Proof of identification of the recipient and the donor

(b) In cases where a recipient is accompanied by his or her own donor, the tissue shall be typed within South Africa in order to determine whether there is a match and the removal of the tissue and its subsequent use must comply with the provisions of the Act and these regulations, as well as the professional and ethical rules of the Health Professions Council of South Africa.

CHAPTER 4

DONATION FROM DECEASED PERSONS THAT DIED OF NATURAL CAUSES

Establishment of Death

11. The death of a person from whose body tissue is to be taken for purposes contemplated in these regulations must be established by at least two medical practitioners, of whom one must have been practicing as a medical practitioner for at least five years after the date on which he or she was registered as a medical practitioner and neither of these medical practitioners may participate directly or indirectly in the transplantation of tissue removed from the body of that person into the body of a living person.

Removal of organ and tissue from deceased persons that died of natural causes

12. The body of a deceased person may be claimed for burial in the case of natural death by the spouse, partner, major child, parent, guardian, major brother or major sister or grandparent of the deceased, in the specific order as listed or by any other person who is authorized to do so in terms of any law or court order irrespective of whether or not the donated tissue has been removed from the deceased person. (Netty to find out what is meant by this regulation)

13. Where the deceased is an unidentified person and after all steps required in terms of the Act and these regulations, have been taken by the South African Police Service to identify the deceased person and locate his or her family, they may provide an affidavit explaining that the person could not be identified or that the family could not be traced and the Director-General or a formally delegated official may then grant permission for tissue removal.

CHAPTER 5

ALLOCATION OF DONOR ORGANS

Allocation and use of human organs and tissue from a deceased person and keeping of records, registers and returns

14. Allocation of organs obtained from the body of a deceased person in the circumstances contemplated in section 62 of the Act must be based purely on the clinical needs of the intended recipient and may not take into account the race, religious beliefs and political affiliation, culture, language or any other aspect of the deceased person's life that has no bearing on the physical state or quality of the tissue in question.

15. (1) A register must be created and maintained by-

(a) the head of the transplant unit of the particular institution where transplants are being performed or the institution that has removed any organ or tissue in terms of Sections 59, 60, 62, 63 and 64 of the Act; or

(b) any authorized institution that receives or deals in tissue or organs.

(2) A person in charge of an institution referred to in paragraph (a) and (b), as the case may be, shall enter, or cause to be entered, not later than the day following such removal of any organ or tissue, the particulars referred to in sub-regulation (3).

(3) The following particulars shall be recorded in the record mentioned in sub - regulation (1);

(a) The chronological serial number for each transplant or procurement for each year.

(b) The date of the transplant or procurement

(a) The name, address, gender, age and nationality of the recipient and the file number where applicable.

(b) The relationship of the donor to the recipient and whether the transplant is categorized as "living related", "unrelated living" or "cadaver" donor.

(c) The names of the surgeons or doctors involved in the transplant and care of the recipient.

(d) The name of the surgeon or doctors that removed the organ or tissue.

(e) The actual place where the organ or tissue was removed

(f) Any further information that is deemed to be necessary.

(4) A record referred to in sub-regulation 15(1) shall-

(a) be kept in accordance with section 17 of the Act; and

(b) unless where the Minister determines otherwise in writing, be retained for a minimum period as required by the National Archives of South Africa Act, 1996(Act No. 43 of 1996)

16. Every authorized institution and transplant units must monthly provide the Department with the information contained in their register.

17. The Department shall keep a national database, in which details of all transplant records received from authorized institutions or transplant units, will be collated.

CHAPTER 6

GENERAL AND SUPPLEMENTARY PROVISIONS

Payment in connection with the donation of organ and or tissue

18. No person who-

(a) contemplates receiving or is about to receive tissue shall offer or provide any financial or other reward to the donor or any other party, except as provided for in section 60 of the Act; or

(b) acts, or acted as a facilitator in the procurement, supply or donation of tissue shall offer or promise any form of financial or other reward to the donor, recipient or another party, whether such offer is on his or her own behalf or on behalf of another party.

Prohibition of disclosure of certain information.

19. No person shall publish to any other person any facts whereby the identity of the person whose body or any specific tissue thereof has been donated, may be established, unless written consent thereto was granted in writing by the donor or any person authorized to give such consent in terms of any law or court order.

20. No person shall publish to any other person any fact whereby the identity of the recipient of any tissue or organ removed from another person before or after the death of the said person, may be established, unless-

(a) in case of a recipient who is still alive at the time of such publication or before such publication granted his or her consent thereto in writing; or

(b) in the case of a recipient who at the time of such disclosure has died-

(i) the recipient before his or her death granted consent to such publication in writing; or
(ii) the recipient did not before his or her death indicate in any manner that he or she would not be prepared to grant such consent and the spouse, partner, major child, parent, guardian, major brother or major sister of the recipient before such publication granted consent thereto in writing.

CHAPTER 7

APPOINTMENT AND FUNCTIONS OF INSPECTOR OF ANATOMY AND INVESTIGATING OFFICERS

Inspector of Anatomy

21. The head of the provincial department in each province shall appoint a person in the provincial department as an inspector of anatomy who will have the same powers and functions referred to in sections 81, 82, 84, 85, 86 and 87 of the Act.

22. An inspector of anatomy shall exercise the powers and perform the duties conferred or imposed upon or delegated or assigned to him or her by or under these regulations, subject to the control and directions of the head of the provincial department.

23. An inspector of anatomy shall exercise his or her powers and perform his or her duties in an area defined by the head of the provincial department.

Investigating Officers

24. The head of the provincial department may appoint any person who is not in the full-time employment of the State as an investigating officer to investigate any matter in terms of these regulations or may appoint such investigating officer to assist an inspector of anatomy

with any matter which falls within the powers and duties of such an inspector of anatomy.

25. An investigating officer may, subject to the control and directions of the head of the provincial department and for the purposes of the investigation for which he or she has been appointed, exercise any power conferred on an inspector of anatomy under regulation 26.

Powers of inspector of anatomy

26. An inspector of anatomy may-

(1) at any reasonable time for the proper performance of his or her functions and without prior notice enter any premises-

(a) in or upon where a human body or tissue is used or is reasonably suspected to be used for any purpose referred to in section 56 of the Act; and

(b) in or upon which the production from tissue of any therapeutic, diagnostic or prophylactic substance or the supply of such substance so produced is carried on or is reasonably suspected to be carried on;

(2) examine any such premises or body, tissue, product or substance or other object found therein or thereon or any activity or process carried out, on, in or upon those premises, and may open any package or container in or upon those premises which contains or is suspected to contain such body, tissue, product, substance or other object, in order to ascertain whether the provisions of the Act and these regulations with regard to those premises or that body, tissue, products, substance, other object, activity or process are being complied with;

(3) at any time demand from any person in or upon any such premises that he or she forthwith or at a time and place determined by the inspector produce to her or to him any register, record or other document which is in the possession or custody or under the control of that person or any other person on his or her behalf;

(4) examine such a register, record or other document and require from any person referred to in sub-regulation (3) an explanation of anything appearing therein, and make copies thereof of extracts therefrom, or seize such a register, record or other document, if in her or his opinion it may afford evidence of an offence in terms of the Act or these regulations;

been employed in or upon such premises or to have possession or custody of or control over anything referred to in this regulation;

(6) order any person contemplated in sub- regulation (3) or (5) to appear before him or her at a time and place determined by him or her, and at that time and place question that person with regard to any matter which he or she is investigating;

(7) remove and discard the remains of the human body or tissue which is kept in or upon premises entered by him or her in terms of sub-regulation(1) if he or she deems it advisable, and recover the cost in connection with the removal and discarding from the institution or person under whose care of the body or tissue concerned was, immediately before such removal and discarding.

Offences and penalties

27. Any person who contravenes or fails to comply with any provision of these regulations; shall be guilty of an offence and liable on conviction to a fine or to imprisonment or to both such fine and imprisonment.

ANNEXURE "A" – DONOR CONSENT FORM

ANNEXURE "B" – "CRITERIA FOR ORGAN DONATION AND TRANSPLANTATION"

ANNEXURE "C" – APPLICATION FOR NON-RELATED DONOR TRANSPLANT (RSA & FOREIGN NATIONALS)

ME TSHABALALA-MSIMANG
MINISTER OF HEALTH

Annexure A

Consent Form: Donor

I ----------, have had the short-term peri-operative complications fully explained to me. I have had the long-term implications fully explained to me. I understand that these complications might very rarely occur and in no way will I hold the operating surgeons responsible for these complications if they do occur. However, should negligence be the cause of any complication, the usual liability claim may be sought.

Signed:

1. Doctor who explained the procedure ----------
2. Witness ----------
3. Patient (donor) ----------

Consent Form: Donor and Recipient

I, the undersigned, ----------, agree to have my blood tested for HIV, Hepatitis and other sexually diseases.

I understand that these results will be kept confidential if they are positive. I also understand that if they are positive, I will not be permitted to donate any organ in the future nor receive a kidney transplant.

Signed---------- Print name----------

Witness 1)---------- Print name----------

Witness 2)---------- Print name----------

Annexure B

CRITERIA FOR SELECTION OF DONORS FOR TRANSPLANTATION

A. Deceased donor, organ/tissue transplantation

Selection of Donors

The decision to utilize the organs or tissues of a potential donor is based on the following criteria

- Establishment and confirmation of brain death according to standard protocol
- Assessment of the suitability of the organs involved as per standard protocol
- The availability of consent from relatives or a directive of intent to be a donor from the deceased (such as a donor card)
- The exclusion of communicable diseases and malignancy or other contra indications to utilization of donor organs as per standard protocol
- The ability to maintain circulation or organ/tissue viability until organs/tissues can be removed for preservation and/or transplantation

Allocations of organs from deceased donors

The allocation of deceased donor organs to a potential recipient is based on the following criteria, weighted to accommodate specific requirements of the type of transplant and the needs of the patients on the waiting list according to established protocols of the region or facility

- Suitable ABO matching if applicable
- Suitable cytotoxic antibody screening
- Suitable HLA compatibility if applicable
- Suitability of size and age if applicable
- Medical condition and degree of urgency if applicable
- Time on the waiting list if applicable

B. Living donor renal transplantation

Living donor transplantation (related or unrelated) should be encouraged because of the shortage of deceased donor organs

Criteria for selection of living donors

- Living donors must be aged 18 years or older
- Fully informed consent should be obtained from both donor and recipient as pertains to risks and benefits of the procedures
- Both donor and recipient should be recorded in a Transplant Database and lifetime follow up must be established

Related living donors

- For related living donors there is no need for a central regulatory mechanism, provided the genetic relationship can be shown to fall within a defined category as follows:

Natural parents and children	Parents and children
Brothers and sisters of whole/half blood	Siblings
Brother/sister of whole/half blood of a natural parent	Aunts and uncles
Children of brothers/sisters of whole/half blood	Nieces and nephews
Natural children of brother/sister of whole/half blood of a natural parent	Cousins

- Donors must satisfy medical, ethical and psychiatric criteria for selection as per established protocols
- All donors and recipients in a living donor transplant program must be assessed and found suitable by a multi-disciplinary transplant selection panel

Unrelated living donors

- The motives of the donor should be assessed to be altruistic and in the best interest of the recipient, not self serving or for profit
- Unrelated donors may include but not be limited to spouses, friends and acquaintances
- Medical investigations for both donor and recipient should conform to standard protocols
- Donor and recipient should undergo psychological assessment by an independent and suitably qualified social worker or psychologist to ensure that no form of coercion exists and that both parties are fully informed and understand the implications of the procedures
- Application to perform unrelated living donor transplant procedures must be forwarded to the relevant office at National Department of Health.
- Applications must be approved by the Ministerial Advisory Committee (MAC) or another committee established for this purpose

C. Other transplants

Recipients and donors are selected according to guidelines set by the transplant centres

Annexure C

Kidney Transplant Request

Unrelated living Donor

Information to be supplied

A. <u>Prospective Recipient and Donor</u>

1. Full personal particulars – include social status, occupation, functionality and habits.

2. Full clinical details – history, physical examination (include height and weight). Exact diagnosis and cause of Chronic Renal Failure

3. Current stage of primary disease, complications, co-morbidity, treatment (drug, non-drug) *IN CASE OF THE RECIPIENT*

4. Psychological assessment or by social worker.

5. Consent Form

6. Full workup details as follows: (NOT MORE THAT SIX MONTHS OLD RESULTS)
   a. Blood group
   b. Tissue typing and MLC
   c. Liver function
   d. Electrolytes, Na, K, Ca, Mg, Random Glucose, Lipogram
   e. Full blood count, INR, ESR
   f. Urine-protein, sugar, blood, microscopy
   g. HbsAg, Hep C
   h. HIV
   i. CMV, IgM, IgG
   j. VDRL
   k. Creatinine clearance
   l. Chest X-ray
   m. ECG – Resting
   n. Stress ECG where indicated

7. Special Investigations
   a. Abdominal ultrasound to confirm the presence of two kidneys
   b. Renal Agiogram – for the renal ureteric anatomy.