

## GOVERNMENT NOTICES • GOEWERMENTSKENNISGEWINGS

### DEPARTMENT OF HEALTH

NO. 556

09 JUNE 2017

#### NATIONAL HEALTH ACT, 2003

##### REGULATIONS RELATING TO HUMAN GAMETE BANKS

The Minister of Health intends, under section 90(1) read with section 68(1)(f) of the National Health Act, 2003 (Act No. 61 of 2003) make Regulations in the Schedule.

Interested persons are invited to submit any substantiated 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: Ms P Netshidzivhani at [Pakiso.Netsidzivhani@health.gov.za](mailto:Pakiso.Netsidzivhani@health.gov.za)) within one month of this notice.



Dr Aaron Motsoaledi

Minister of Health, MP

Date

3/5/2017

## 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 –

**“Central data bank”** means an electronic database into which all information regarding storage and distribution of donated gametes is stored and managed;

**“Competent person” in relation to:-**

- (a) oocytes means a medical practitioner registered with the Health Professions of South Africa (HPCSA) with expertise as a specialist gynaecologist and as a sub-specialist in Reproductive Medicine, or a trainee in Reproductive Medicine in a training unit under the supervision of a registered HPCSA sub-specialist; and
- (b) sperms means a medical doctor registered with the HPCSA as an endocrinologist;

**“cryopreservation”** means freezing at low temperatures;

**“database”** means a database contemplated in regulation 3(2)

**“gamete bank”** means an organisation, institution or person that provides or engages in one or more services involving withdrawal gametes from living individuals for storage and distribution purposes and is authorised in terms of regulation 3 of these regulations;

**“gamete donor”** means a living person from whose body a gamete or gametes are removed or withdrawn;

have one normally functioning and one faulty gene (i.e. a heterozygote);

**“sperm”** means the male gamete;

**“stimulation”** means any process, method or procedure used to facilitate the withdrawal of gametes; and

**“the Act”** means the National Health Act, 2003 (Act No. 61 of 2003).

### **Application of the Regulations**

2. These Regulations only apply to the withdrawal, storage and distribution of gametes from living persons.

### **Application for authorisation**

3. (1) A competent person shall apply for authorisation of a gamete bank to the Director General indicating why authorisation is required.
- (2) The Director-General shall keep a database of authorised gamete banks.
- (3) The application referred to in sub regulation (1) shall contain the following information:
  - (a) the name and nature of the application;
  - (b) location of the premises where business is to be conducted;
  - (c) an indication of how records and data shall be kept;
  - (d) the quality management system to be used;
  - (e) details of the competent person;
  - (f) any other information the Director-General may consider necessary for the consideration of the application; and

- (4) The Director-General may, on application in terms of sub-regulation (1):
- (a) cause the applicant to be investigated; or
  - (b) obtain such further information as he or she deems necessary for the consideration of the application;
  - (c) authorise the applicant concerned as a gamete bank, subject to such conditions as he or she may determine; and
  - (d) Where such applicant is not approved, the Director General shall notify the applicant in writing accordingly, stating the reason for such non-authorisation.

#### **Establishment of a Central Data Bank**

4. The Director-General shall establish an electronic central database into which all information regarding the donated gametes, their storage and distribution is stored.

#### **Age of prospective gamete donors**

5. The competent person must not:-
- (a) withdraw oocytes from a donor older than 34 years; and
  - (b) withdraw sperms from a donor older than 46 years.

#### **Advertising for recruitment of gamete donors**

6. The advertisement or an invitation of potential donors to donate gamete must include or inform the potential donor of the risk associated oocytes donation with particular emphasis on the health risk as result of multiple donations.

### **Removal or withdrawal and storage of gametes**

7. (1) No person, except competent persons, may remove or withdraw a gamete or cause a gamete to be removed or withdrawn from the body of a gamete donor for the purpose of storage; and
- (2) Once gametes are removed in terms of sub-regulation (1), they shall be cryopreserved.
- (3) The competent person may only withdraw gamete from a donor after satisfying himself or herself that the donor understood the risk associated with oocytes or sperm donation with particular emphasis on maximum number of times a female gamete donor can donate.

### **Screening of donors for removal or withdrawal of gametes**

8. A competent person who intends to remove or withdraw a gamete, or cause a gamete to be removed or withdrawn from the body of a gamete donor, shall, before such removal or withdrawal –
  - (a) ensure that if a gamete donor file has not previously been opened in respect of that gamete donor, open such a file, to which a unique identification number shall be allocated in respect of the gamete donor;
  - (b) ensure that the information obtained in paragraph (a) is submitted to the Central Data Bank;
  - (c) obtain a signed statement from the gamete donor stating whether the gamete donor has previously made a donation of gametes and, if so, where and when that donation of gametes took place;
  - (d) in the case of a known female donor, ascertain from the Central Data Bank whether the donor has reached the maximum limit of six donations;
  - (e) in the case of a known male donor, ascertain from the Central Data Bank whether gametes of the donor has been used to produce maximum of twelve live births;



- (f) obtain informed consent from the gamete donor relating to –
  - (i) physical examination and questioning by a competent person;
  - (ii) the removal or withdrawal a gamete for testing, analysing or other processing as the competent person may deem necessary;
  - (iii) particulars contemplated in regulation 9(1)(a)(ii), (iii) and (iv), (b) and (c) are recorded; and
  - (iv) to particulars contemplated in regulation 9(2)(c) being submitted to the Central Data Bank;
- (f) ascertain the age of the gamete donor;
- (g) ascertain that the gamete donor has on two occasions, not more than three months apart and one month prior to that donation of gametes, undergone –
  - (i) medical tests for sexually transmissible diseases; and
  - (ii) a semen analysis, in the case of a male gamete donor;
- (h) ascertain that in the case of a female gamete donor, the donor has undergone a gynaecological examination prior to stimulation for the withdrawal of gametes; and
- (i) question such gamete donor concerning her or his family history, especially with regard to any possible genetic condition or carrier status and mental illness in respect of any child, brother, sister, parent or grandparent of such gamete donor.

**Gamete donor files, availability of information and destroying of gametes**

9. (1) The competent person must immediately record the following information and documents in the gamete donor's file before a gamete is removed or withdrawn-
- (a) the gamete donor's –
    - (i) full name, surname, date of birth and identity number;
    - (ii) age, height, mass, eye colour, hair colour, complexion, population group, nationality, sex, religion, occupation, highest educational qualification and fields of interest;

- (iii) family history referred to in regulation 8(i); and
  - (iv) wishes in respect of the number of live births for which her or his gametes may be used.
- (b) the particulars of medical tests for genetically transmissible disorders or for infectious diseases, or genetic evaluation of the gamete donor;
- (c) particulars of any evaluation of the psychological suitability of the gamete donor to donate a gamete;
- (d) particulars of each donation of gametes made by the gamete donor, including the date on which the donation of gametes was made;
- (e) the informed consent and documents contemplated in regulation 8(e);
- (f) results of the tests and the analysis or examination contemplated in regulation 8(e) to (g); and
- (g) any other relevant document or information that the competent person may request.
- (2) The competent person—
  - (a) shall retain the gamete donor file in safe-keeping and shall not destroy the file, except with the written permission of the Director-General;
  - (b) shall make the particulars set out in sub-regulation (1)(a)(ii), (iii) and (iv), (b), (c) and (f), together with the identification number referred to in regulation 8(a), available to the end user;
  - (c) shall furnish the Central Data Bank before 31 January of each year with the following particulars regarding the preceding year in respect of the gamete donor:
    - (i) the identification number of the gamete donor file; and
    - (ii) the number of donations of gametes, with the dates on which the donations were made and distributed;
  - (d) shall not make the gamete donor file, or information therefrom, available to any person other than a person acting

under her or his supervision, except in terms of legislation or a court order.

- (e) shall immediately, after, consulting with the Central Data Bank and informed that the gamete donor has reached the maximum limit of donations –
  - (i) make a conspicuous note to that effect in the gamete donor file;
  - (ii) make available this information to the Central Data Bank;
  - (iii) destroy all gametes donated by such gamete donor and any gametes that the competent person has in storage, unless the Minister consents to the competent person keeping those gametes for distribution as contemplated in regulation 11(1)(a); and
  - (iv) inform the donor of the actions taken as in terms of sub-paragraph (iii).

#### **Compensation in respect of the withdrawal or removal of gametes**

10. A person from whose body a gamete has been removed or withdrawn may be reimbursed for any reasonable expenses incurred by him or her in order to donate a gamete as contemplated in section 60(4)(a) of the Act.

#### **Restriction on donation of gametes**

11. A competent person –

- (1) (a) shall not remove or withdraw a gamete, or cause a gamete to be removed or withdrawn, from the body of a gamete donor for storage if the competent person has knowledge or suspects that the donor has reached the maximum limit of donations contemplated in regulation 8(d) and (e);
- (b) shall, where the competent person has information or suspects that the gamete donor has reached the maximum



limit of donations contemplated in paragraph (a), inform that gamete donor that he/she may not make any further donation of gametes; and

- (c) must, immediately relay all the information relating to such gamete donor, the removal or withdrawal of a gametes, to the Central Data Bank contemplated in regulation 6.

#### **Place where and person who effects a donation**

- 12. (1) Gamete donation must only be effected at an authorised institution; and
- (2) Only a competent person may effect donation.

#### **Control over storage and destroying of gametes**

##### **13. No gamete –**

- (a) that has not been imported, removed or withdrawn in terms of the provisions of the Act or these Regulations;
  - (b) from a gamete donor of whom the results of the tests, analysis or examination referred to in regulation 9 (1)(f), as the case may be, are not available yet; or
  - (c) from the gamete donor younger than 18 years of age except in the case of a medical indication,
- may be stored.

#### **Recording of names of authorised institutions and competent persons in the database**

- 14. (1) The Director-General shall keep an electronic database with particulars of –
  - (a) authorised institutions contemplated in Regulation (3), where gamete donation may be effected; and
  - (b) a competent person(s) who effects such donation(s).
- (2) A competent person who has changed her or his name or address of practice or a person in charge of an authorised institution, the name or address of which has been changed,

shall within 30 days of such change inform the Director-General in writing of such change.

#### **Deletion of names from database**

15. (1) The Director-General shall delete from the database the name of -

- (a) a competent person who has died;
- (b) a competent person who requests the Director-General in writing to remove her or his name from the database;
- (c) a competent person who was found to have contravened or failed to comply with the provisions of these regulations; or
- (d) an authorised institution in the case where the owner, manager or person in charge of such institution requests the Director-General to remove the name of such a place from the database.

(2) The Director-General may -

- (a) after an inspection of an authorised institution or any activity or process connected with gamete donation of such an institution;
- (b) on the grounds of a report by any -
  - (i) health officer contemplated in Section 80 of the Act; and
  - (ii) any other officer of the Department specifically so designated in terms of sections 77 and 78 of the Act;
- (c) on the grounds of a complaint, charge or allegation of which she or he has knowledge or which may come to her or his notice in connection with such authorised institution, activity or process and after any inspection or collection of information in connection with such complaint, charge or allegation that she or he may deem necessary or expedient; or
- (d) in the case where she or he is of the opinion that on or in such place conditions exist which are dangerous or harmful or likely to be dangerous or harmful to health,

provisionally delete the name of such place from the database, and must in writing notify the person in charge of such authorised institution accordingly.

- (5) Any notice referred to in sub-regulation (4) shall provide sufficient details of grounds for the deletion.
- (6) The deletion made in terms of this regulation shall-
  - (a) be entered in the database; and
  - (b) be valid until the danger or situation which gave rise to such suspension has, to the satisfaction of the Director-General been removed: provided that if such danger or situation is not removed or rectified within a period of three months from the date of notice contemplated in sub-regulation (1), such authorised institution must be deleted from the database and may not store gametes.

#### **Prohibition of disclosure of certain facts**

- 16. No person shall disclose the identity of any person who donated a gamete(s).

#### **Appeals**

- 17. (1) (a) A person aggrieved by the decision of the Director-General in terms of these regulations may within 14 days of receiving such decision, appeal in writing to the Minister against such decision.
- (b) A copy of the appeal shall be sent to the Director-General for his or her information and response if necessary.
- (2) An appeal in terms of sub-regulation (1) shall clearly state the grounds on which such appeal is lodged.
- (3) The Minister may confirm, amend or revoke a decision taken by the Director-General in terms of the provisions of these

regulations and thereafter inform the appellant of her or his decision.

#### **Offences and penalties**

18. Any person who contravenes or fails to comply with any provision of these regulations commits an offence and is liable on conviction to a fine or imprisonment for a period not exceeding 10 years, or to both such fine and imprisonment.

#### **Short title**

19. These Regulations are called Regulations Relating to Human Gametes Banks, 2017.