Government Gazette
Staatskoerant

REPUBLIC OF SOUTH AFRICA
REPUBLIEK VAN SUID AFRIKA

Vol. 669 | 25 March Maart | 2021 | No. 44321

Contents

DEPARTMENT OF HEALTH

NO. 251 **25 March 2021**

NATIONAL HEALTH ACT, 2003

REGULATIONS RELATING TO ASSISTED CONCEPTION OF PERSONS

The Minister of Health intends, in terms of section 68(1)(*l*) of the National Health Act, 2003 (Act No. 61 of 2003), to make Regulations in the Schedule.

Interested persons are invited to submit any substantiated comments or representations on the proposed regulations to the Director-General of Health, Private Bag X828, Pretoria, 0001 (for attention of the Ms Lineo Motopi, Medical Scientist: Chapter 8 and Laboratories, lineo.motopi@health.gov.za), 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 bears such meaning and, unless the context otherwise indicates –

"assisted conception" means an *in vitro* fertilisation and includes an intracytoplasmic sperm injection and intrafallopian tube embryo transfer;

"authorised institution" means an *in vitro* fertilisation (IVF) clinic authorised in terms of regulation 3 of these regulations;

"central data bank" means an electronic database contemplated in Regulation 6 into which all information regarding use of individual donated gametes and assisted conception treatment outcomes is stored and managed;

"competent person" means a sub-specialist in Reproductive Medicine registered with the Health Professions Council of South Africa (HPCSA), or a trainee in Reproductive Medicine in a training unit working under the

supervision of a registered sub-specialist in Reproductive Medicine;

"cryopreserved" means freezing at very low temperatures (between - 80ºC to -196 ºC) of egg, sperm, embryos or ovarian tissue by an authorised institution;

"database" means a database contemplated in regulation 15(1);

"donor" means a person over the age of 18 who is eligible to have gametes withdrawn or procured in terms of regulation 4;

"egg" means a female gamete withdrawn from an eligible donor for the purpose of assisted conception;

"embryo transfer" means the placing of an embryo into the uterus or fallopian tubes of the recipient;

"gamete donor" means a living person from whose body a gamete or gametes are withdrawn or procured after stimulation, for the purpose of donation for assisted conception;

"genetic carrier" means an individual who has a disease-causing mutation, but will not develop the condition and who has one normally functioning and one faulty gene (i.e. a heterozygote);

"inspection team" means persons employed or nominated by the Director-General for the specific purpose of inspecting fertility clinics;

"intracytoplasmic sperm injection" means a process involving microscopic technology performed in an authorised institution to bring about fertilisation of an egg with a single sperm outside the body;

"intrafallopian tube embryo transfer" means transfer of zygotes or embryos into the fallopian tube;

"in vitro fertilisation" means the process of fertilisation of an egg with a sperm outside the body in an authorised institution by a competent person;

"in vitro fertility (IVF) clinic" an institution authorised to withdraw gametes from female donors, procure donated gametes from male donors and perform *in vitro* fertilisation of recipients;

"recipient" means a female person into whose uterus or womb or fallopian tubes, an embryo created using gamete from a donor is to be placed for the purpose of assisted conception;

"sperm" means the male gamete procured for the purpose of assisted conception;

"serious genetic condition" means a disease-causing genetic condition which compromises physical or mental ability and may be lethal;

"sex linked genetic condition" means a genetic condition that is linked to either the Y or X sex chromosomes resulting from a disease-causing mutation for a genetic disorder carried on either of the sex chromosomes;

"sex limited genetic condition" means disease-causing mutations present in

both sexes of sexually reproducing species that are expressed in only one sex and remain 'turned off' in the other;

"stimulation" means any process, method or procedure used to facilitate the withdrawal of a gamete or gametes; and

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

Application of regulations

2. These Regulations apply to donated gametes from and for use in all *in vitro* fertilisation procedures on living persons performed in an *in vitro* fertilisation clinic.

Application for authorisation certificate

3. (1) A competent person must apply on application form attached hereto as **Appendix** 1, to the Director- General for authorisation to legally operate as an *in vitro* fertilisation clinic.

(2) The application referred to in subregulation (1) must contain the following information:-

(a) location of the premises where business is to be conducted;
(b) an indication of how records and data are kept;
(c) the quality management system used;
(d) details of the competent person; and
(e) any other information the Director-General may deem necessary for the consideration of the application.

(3) The Director-General must, on application in terms of subregulation (1)-

(a) cause the premises to be inspected in terms of the inspection tool developed by the Director-General;
(b) obtain such further information as the Director-General deems necessary for the consideration of the application; or
(c) authorise the applicant concerned to operate legally as an *in vitro* fertilisation clinic, subject to such conditions as he or she may determine.

(4) (a) The Director-General must keep a database of authorised *in vitro* fertilisation clinics.

(b) The database must be updated once a year and be published online and in the *gazette* in order to ensure that the public has access to this information.

Withdrawal or procurement and storage of gametes

4. (1) No person, except a competent person, may withdraw a gamete or cause a gamete to be withdrawn from the body of a female gamete donor for the purpose of assisted conception and ascertain that the gamete donor has not donated more than six times.

(2) For purposes of assisted conception, male gametes must be procured only after self-stimulation.

(3) The gametes donated in terms of subregulations (1) must be cryopreserved for future assisted conception.

Compensation in respect of withdrawal or procurement of gametes

5. (1) A person from whose body a gamete has been withdrawn or procured 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.

(2) The Director-General must, after consultation with stakeholders including patients, donors or public gamete banks and competent persons, from time to time publish guidelines regarding re-imbursement of female and male donors.

Establishment of a Central Data Bank

6. (1) The Director-General must establish an electronic central database into which all information regarding the use of individual donated gametes and assisted conception treatment outcomes is stored; and

(2) Information in the database must be treated as confidential and must not be disclosed to third parties.

Restriction on donation of gametes

7. (1) A competent person must not withdraw-

(i) from the body of a gamete donor for a recipient if the competent person has information from the central data bank that a maximum of 12 live births has been reached, for a maximum of six recipients, through assisted conception using gametes of that gamete donor; or

(ii) from the body of a female donor for a recipient if the competent person has information that the donor has donated six times irrespective of the number of live births referred to in subparagraph (i).

(2) A competent person must not use the gamete of male donor if the competent person has information or supposed to have information from the central data bank that a maximum of 12 live births has been reached, for a maximum of six recipients, through assisted conception using gametes of that gamete donor.

(3) A competent person must, where donated gametes have been used and resulted in twelve live births contemplated in subregulations (1) and (2), inform that gamete donor that he or she may not make any further donation of gametes to a new recipient.

(4) A competent person must, immediately relay all information relating to such gamete donor, the procurement or withdrawal of a gamete and the *in vitro* fertilisation to the central data bank contemplated in regulation 6.

Prerequisites for procurement or withdrawal of gametes

8. A competent person who intends to procure, withdraw a gamete, or cause a gamete to be withdrawn from the body of a gamete donor, must, before such procurement or withdrawal –

(a) ensure that if a gamete donor file has not previously been opened in respect of that gamete donor, that such a file be opened, to which a unique identification number must be allocated in respect of the gamete donor;

(b) ensure that the information obtained in terms of paragraph *(a)* is submitted to the central data bank;

(c) ascertain from the central data bank that not more than twelve live births have been reached through the assisted conception of a person with the gametes of that gamete donor, or in the case of a female donor that the donor has not donated more than six times irrespective of the number of live births;

(d) obtain signed informed consent 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;

(e) obtain signed informed consent from the gamete donor relating to –

(i) physical examination and questioning by the competent person;

(ii) the withdrawal of 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), (iv), *(b)*, *(c)* and *(f)* being made available to the recipient and the competent person who is to perform the assisted conception; and

(iv) particulars contemplated in regulation 9(2)*(c)* being submitted to the central data bank;

(f) ascertain that the age of the female gamete donor is between 18 to 34 years and for male gamete donor that the age is between 18 – 46 years with reference to a legally recognised form of identification;

(g) ascertain that the gamete donor has one month prior to that donation of gametes, undergone –

(i) medical tests for sexually transmitted 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;

(i) question such gamete donor concerning her or his family history, including, but not limited to:

(i) possible genetic conditions and inherited diseases;

(ii) 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) A competent person must immediately record the following information and include a document in the gamete donor's file before a gamete is withdrawn:

(a) The gamete donor's –

;(i) full name, surname, date of birth and identity number or passport 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) subject to regulation 7(1) wishes in respect of the number of live births achieved by assisted conception 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 written and signed consent form and documents contemplated in regulation 8(e);

(f) results of the tests and the analysis or examination contemplated in regulation 8*(e)* and *(g)*; and

(g) any other relevant document or information that the competent person may request.

(2) The competent person–

(a) must retain the gamete donor file in safe-keeping and must not destroy the file, except with the written permission of the Director-General;

(b) must make the particulars set out in subregulation (1)*(a)*(ii), (iii) and (iv), *(b)*, *(c)* and *(f)*, together with the identification number referred to in regulation 8*(a)*, available to the recipient and the competent person who is to effect the assisted conception of the recipient;

(c) must furnish the central data bank before 31 January of each year with the following particulars regarding the preceding or previous year in respect of the gamete donor:

(i) The identification number of the gamete donor file;

(ii) The number of donations of gametes with dates on which the donations were made; and

(iii) The number of live births reached through the assisted conception from the gametes of the specific gamete donor,

(d) must 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) must immediately, after if it has come to her or his attention that a maximum of 12 live births through assisted conception has been reached from the gametes of a specific gamete donor –

(i) make a conspicuous note to that effect in the gamete donor file;

(ii) make available this information to the central data bank within 30 days;

(iii) destroy all gametes donated by such gamete donor and any gametes that the competent person has in storage,; and

(iv) inform the donor of the actions to be taken as in terms of

subparagraph (iii).

Place where and person who effects assisted conception

10. Assisted conception must only be effected at an authorised institution by a competent person.

Control over Assisted Conception

11. No gamete –

(a) that has not been imported, withdrawn in terms of the provisions of the Act or these regulations; or

(b) obtained from a gamete donor for whom the results of the tests, analysis or examination referred to in regulation 8*(e)* to *(g)*, as the case may be, are not available yet; or

(c) Obtained from a gamete donor younger than 18 years of age, may be used for assisted conception.

Requirements for Assisted Conception

12. (1) A competent person intending to effect the embryo transfer to a recipient must, before effecting the embryo transfer –

(a) ensure that if a recipient file has not previously been opened in respect of that recipient, that such a recipient file is opened, to which a unique identification number shall be allocated in respect of the recipient;

(b) obtain informed written consent from the recipient relating to–

(i) physical examination and questioning by a competent person;

(ii) the withdrawal of a gamete from the body of the donor for the purpose of such testing, analysing or other processing of that gamete, as the competent person may deem necessary;

(iii) particulars contemplated in regulation 14(2)*(c)* being made available to the central data bank;

(c) ensure that –

(i) the gamete donor's particulars and wishes referred to in regulation 9(1)*(a)*(i) to (iv) are conformed to;

(ii) the recipient's particulars and wishes referred to in regulation 14(1)*(a)*(i) to (iii) are conformed to;

(iii) if the recipient or the gamete donor/s should be a carrier of a serious genetic condition –

(aa) the recipient and the gamete donor are tested to confirm whether they are such genetic carriers; and

(bb) if it is determined that both the recipient and the gamete donors are such carriers, a gamete from that gamete donors is not used for the assisted conception of the recipient;

(cc) If the gamete donor is a carrier, but the recipient is not a carrier, the gamete donor may be used after notifying the recipient of the carrier status of the donor.

(iii) if, on account of the family history of the recipient or the gamete donor, the possibility exists that one of them is a carrier, or both of them are carriers of a genetically transmissible disorder, the recipient or gamete donor, as the case may be, is examined or tested to determine whether she or he is such a carrier, and –

(aa) if it is determined that the recipient is such a carrier, the recipient is informed about the implications thereof; or

(bb) if it is determined that the gamete donor is, or may probably be, such a carrier –

(AA) a gamete from that gamete donor is not used for assisted conception; or

(BB) the competent person who has withdrawn a gamete, or caused a gamete to be withdrawn, from the body of that gamete donor is informed that the gamete donor is, or probably may be, such a carrier.

(2) No more than two zygotes or embryos may be transferred to the recipient during an embryo transfer procedure, unless there is a specific medical indication requiring the contrary.

Prohibition of pre-implantation testing for sex selection

13. Pre-implantation testing for selecting of the sex of an embryo is prohibited except in the case of serious sex linked or sex limited genetic conditions.

Recipient files and availability of information

14. (1) A competent person who effects the assisted conception must immediately record or file the following particulars and documents in a recipient file referred to in regulation 12(1)*(a)*:

(*a*) The recipient's –

(i) full name, surname, and date of birth and identity number;

(ii) family history, especially with regard to possible carrier status for genetic and or mental disorders;

(iii) wishes in respect of the population group of which the gamete donor, whose gametes are to be used for the assisted conception, should be a member and the religion, which the gamete donor should profess, as well as any other wish of the recipient concerning the gamete donor;

(*b*) Particulars of medical tests done for sexually transmissible infections, or communicable diseases in respect of the recipient;

(*c*) Particulars of genetic evaluation made in respect of the recipient;

(*d*) Particulars of an evaluation if indicated made of the psychological or social suitability of the recipient with a view to her assisted conception;

(*e*) the informed written consent contemplated in regulation 12(1)*(b)*;

(*f*) any other relevant document or information that the competent person may obtain, including a document or information regarding a previous assisted conception of the recipient;

(*g*) in the case of *in vitro* fertilisation of or embryo transfer –

(i) the number of embryos effected for the embryo transfer to the recipient;

(ii) the number of embryos used for each embryo transfer procedure as stipulated in regulation 12 (2);

(iii) the number of embryos in storage;

(iv) the number of embryos used for purposes other than embryo transfer; and

(iv) the number of embryos destroyed.

(2) The competent person referred to in subregulation (1) must –

(*a*) retain the recipient file in safe-keeping and must not destroy the file, except with the written permission of the Director-General;

(*b*) not make the recipient file, or information therefrom, available to any person other than a person acting under her or his supervision, except where a law provides for otherwise or a court so orders; and

(*c*) make available to the central data bank before 31 January of each year the following particulars regarding the previous year in respect of the recipient:

(i) the identification number of the recipient file;

(ii) the date on which an assisted conception of the

recipient, was effected,

(iii) the number of *in vitro* fertilisations of the recipient effected;

(iv) the particulars contemplated in subregulation (1)*(g)*; and

(v) the results of each procedure referred to in subparagraph (ii).

Recording of names of authorised institutions and competent persons in database

15. (1) The Director-General must keep an electronic database with particulars of –

(*a*) authorised institutions as contemplated in regulation 3, here assisted conception may be effected; and

(*b*) the competent person or persons who effect such assisted conception at the authorised institution.

(2) The Director-General must delete from the database the name of -

(*a*) a competent person who has died;

(*b*) a competent person who requests the Director-General to remove her or his name from the database in writing;

(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 or where the authorised institution has failed to comply with the provisions of these regulations.

(3) 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, must within 30 days of such change inform the Director-General in writing of such change.

(4) The Director-General may –

(*a*) after an inspection of an authorised institution or any activity or process connected with assisted conception of a recipient in or by such an institution;

(*b*) on the grounds of a report by an inspection team;

(*c*) on the grounds of a complaint, charge or allegation of which she

or he has knowledge of, 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 the Director-General is of the opinion that conditions exist in the authorised institution 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 subregulation (4) shall provide sufficient details of grounds for the deletion.

(6) The deletion made in terms of this regulation must-

(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 subregulation (1), such authorised institution must be deleted from the database and may not perform assisted conception.

Reporting of births by competent person

16. (1) The competent person who effected assisted conception must follow up with the mother and record such birth and information referred to in subregulation (2), within 30 days of such birth.

(2) The information which must be recorded in terms of subregulation (1) shall include, but not be limited to-

(*a*) confirmation of birth;

(*b*) the unique identification number referred to in regulation 12(1)*(a)*; and

(*c*) any genetic disorder or birth defect in the child.

Reporting of disorders and mental illnesses by authorised institution

17. (1) Should it come to the attention of an authorised institution that effected an assisted conception that a child born as a result of the assisted conception displays any genetic disorder or suffers from any mental illness –

(*a*) it should be determined if the cause of the disorder or mental illness can be traced back to the gamete donor or the recipient; and

(*b*) should the disorder or mental illness be traced back to the gamete donor, in writing, notify the Director-General of the disorder or mental illness, any tests carried out with regard to the disorder or mental illness, the results of the tests and their view on the disorder or mental illness.

Prohibition of disclosure of certain facts

18. No Fertility Clinic or staff working in Fertility Clinic must disclose the identity of any person who donated a gamete or received a gamete, or any matter related to the assisted conception of such gametes, or reproduction resulting from such assisted conception except where a law provides otherwise or a court so orders.

Appeals

19. (1) (*a*) A competent person or donors or recipients 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; and

(*b*) A copy of the appeal must be sent to the Director- General for his or her information and response if necessary.

(2) An appeal in terms of subregulation (1) must clearly state the grounds on which such an appeal is lodged.

(3) The Minister may confirm, amend or revoke or vary 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

20. 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 less five years, or to both such fine and imprisonment.

Repeal

21. The Regulations Relating to Artificial Fertilisation of Persons, 2012 published in Government Notice No. R175, Government *Gazette* No. 35099 dated 2 March 2012 are hereby repealed.

Short title

22. These Regulations are called Regulations Relating to Assisted Conception of Persons, 2020.

DR Z.L MKHIZE, MP
MINISTER OF HEALTH
DATE 18/02/2021

APPENDIX 1: APPLICATION FORM

health

Department:
Health
REPUBLIC OF SOUTH AFRICA

APPLICATION FOR AUTHORISATION – IVF CLINIC

NAME OF IVF CLINIC:

COMPANY REGISTRATION NUMBER WITH DTI:

PHYSICAL ADDRESS:

CONTACT DETAILS:

MEDICAL DIRECTOR:

QUALIFICATIONS:

REGISTRATION WITH HPCSA:

CONTACT DETAILS:

EMBRYOLOGIST

QUALIFICATIONS:

REGISTRATION WITH HPCSA:

QUALIFICATIONS:

OTHER TECHNICAL PERSONS

QUALIFICATIONS:

POSITIONS/RANK:

REGISTRATION WITH HPCSA:

QUALIFICATIONS:

POSITIONS/RANK:

16

ACCREDITATION

ACCREDITATION:

STANDARDS: ISO, SABS? OR OTHERS

QUALITY MANAGEMENT SYSTEM:

TESTING LABORATORY ACCREDITED:

STORAGE SYSTEM: