UNIVERSITY OF KWAZULU-NATAL
SCHOOL OF LAW

Regulations on the Use of Artificial Reproductive Technology

revised draft, 23 July 2021

based on the draft regulations published by the Minister of Health for public comment on 25 March 2021,

revised by Professor Donrich Thaldar and Mr Bonginkosi Shozi,
in consultation with Dr Sulaiman Heylen.

DEPARTMENT OF HEALTH

No. R... 2021

NATIONAL HEALTH ACT, 2003

REGULATIONS ON THE USE OF ASSISTED REPRODUCTIVE TECHNOLOGY

The Minister of Health has, in terms of section 68 of the National Health Act, 2003 (Act 61 of 2003), made the Regulations in the Schedule.

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 –

"reproduction using ART" means reproduction that occurs through the use of assisted reproductive technology;

"assisted reproductive technology or ART" means all interventions that include the *in vitro* handling of both human oocytes and sperm or of embryos for the purpose of reproduction. This includes, but is not limited to, IVF and embryo transfer, intracytoplasmic sperm injection ICSI, embryo biopsy, preimplantation genetic testing PGT, assisted hatching, gamete intrafallopian transfer GIFT, zygote intrafallopian transfer, gamete and embryo cryopreservation, semen, oocyte and embryo donation, and gestational carrier cycles.

"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 reproduction using ART outcomes is stored and managed;

"competent person" means a fertility specialist or embryologists as defined herein;

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

"egg" means a female gamete withdrawn from an eligible donor for the purpose of reproduction using ART;

"embryologist" means a person who is registered with the HPCSA as:-
(a) a medical scientist, medical technologist, or clinical technologist with training in reproductive biology and related laboratory procedures, or
(b) a trainee for (a) above, who is working under the supervision of a person contemplated in (a) above;

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

"fertility specialist" means a person who is registered with the HPCSA as:-
(a) a subspecialist in reproductive medicine, or
(b) a trainee subspecialist in reproductive medicine who is working under the supervision of a subspecialist in reproductive medicine;

"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 reproduction using ART;

"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 (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 an embryologist;

"recipient" means a woman who intends to become pregnant through reproduction using ART;

"registry of authorised institutions and persons" means an online registry as contemplated in regulation 17(1);

"sperm" means the male gamete procured for the purpose of reproduction using ART;

"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 reproduction using ART procedures on living persons performed in an authorised institution.

Application for an authorisation certificate

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

(2) The application referred to in sub-regulation (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 sub-regulation (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 record of authorised institutions in the online registry contemplated in regulation 17(1).

(b) These records 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 fertility specialist, may withdraw a gamete or cause a gamete to be withdrawn from the body of a female gamete donor for the purpose of reproduction using ART.

(2) If not used immediately, the gametes donated in terms of sub-regulation 4(1) must be cryopreserved for future reproduction using ART.

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 reproduction using ART 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 fertility specialist must not withdraw-

(i) from the body of a gamete donor for a recipient if the fertility specialist has information from the central data bank that a maximum of 12 live births has been reached, for a maximum of 6 recipients, through reproduction using ART using gametes of that gamete donor; or

(ii) from the body of a female donor for a recipient if the fertility specialist has

information that the donor has donated 6 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 reproduction using ART using gametes of that gamete donor.

(3) A competent person must, where donated gametes have been used and resulted in 12 live births as contemplated in sub-regulations (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.

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 12 live births have been reached through the reproduction using ART 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 6 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 10(1)*(a)*(ii), (iii), (iv), *(b)*, *(c)* and *(f)* being made available to the recipient and the competent person who is to perform the reproduction using ART; and

(iv) particulars contemplated in regulation 10(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, 1 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) genetic carrier status; and mental illness in respect of any child, brother, sister, parent or grandparent of such gamete donor.

The use the gametes of a person who is known to the recipient

9. (1) In the event that a recipient intends to use the gametes of a person who is known to her for reproduction using ART, but who is not the recipient's spouse or permanent life partner, the treating fertility specialist must advise the recipient of the content of regulation 9.

(2) In a situation as contemplated in sub-regulation (1), the following persons must be evaluated by a clinical psychologist:

(a) The recipient;

(b) The recipient's spouse or permanent life partner, if any;

(c) The gamete donor;

(d) The gamete donor's spouse or permanent life partner, if any.

(3) The objective of the evaluation contemplated in sub-regulation (2) is to ascertain whether the expectations of the persons listed in sub-regulation (2) regarding the involvement of the persons listed in sub-regulation (2)(c) and (2)(d) with the prospective child and the recipient's family are aligned.

(4) A clinical psychologist who conducts the evaluation as contemplated in sub-regulation 9(2) must interview the persons listed in sub-regulation (2), either individually or together in groups, and then draft a written report stating whether he or she is satisfied that expectations are aligned as contemplated in sub-regulation (3), and also give his or her reasons in brief.

(5) The evaluation report contemplated in sub-regulation (4) must be made available to all the persons listed in sub-regulation (2).

(6) The treating fertility specialist in a situation as contemplated in sub-regulation (1), may only proceed with the reproduction using ART of the recipient if the fertility specialist is provided with an evaluation report contemplated in sub-regulation (4), and if such evaluation report states that the clinical psychologist is satisfied that expectations are aligned as contemplated in sub-regulation (3).

Gamete donor files, availability of information and destroying of gametes

10. (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), his or her 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 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 recipient and the competent person who is to effect the reproduction using ART 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 reproduction using ART using 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 reproduction using ART 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 reproduction using ART

11. Reproduction using ART must only be effected at an authorised institution by a competent person.

Control over reproduction using ART

12. 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 reproduction using ART.

Requirements for reproduction using ART

13. (1) A fertility specialist 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 fertility specialist;

(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 16(2)© being made available to the central data bank;

(c) ensure that –

(i) the gamete donor's particulars and wishes referred to in regulation 10(1)*(a)*(i) to (iv) are conformed to;

(ii) the recipient's particulars and wishes referred to in regulation 16(1)*(a)*(i) to (iii) are conformed to;

(iii) if the recipient or the gamete donor/s should be a genetic 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 reproduction using ART of the recipient;

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

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

(AA) a gamete from that gamete donor is not used for reproduction using ART; 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 genetic 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 otherwise.

Human heritable genome editing

14. (1) The genomes of gametes and embryos may only be edited if such edit is part of a pre-clinical trial or clinical trial that is: –

(a) approved by a health research ethics committee registered as such with the National Health Research Ethics Council, and

(b) in the event of a clinical trial, registered with the South African Health Products Regulatory Authority.

(2) Sub-regulation (1) shall cease to have effect after ten years from the date of promulgation of these regulations, unless the Minister of Health gives notice in the Government Gazette that the effect of the sub-regulation is extended for a specified period not exceeding five years.

(3) The genomes of gametes and embryos may not be edited if such an edit is likely to have an effect on the prospective child that would constitute either a civil or criminal wrong in law if caused by an act by a parent toward an existing child.

(4) Subject to sub-regulation (1) and sub-regulation (3), the recipient and, if applicable, the recipient's spouse or life partner, have the right to decide whether to have the genomes of their gametes or embryos edited.

Pre-implantation testing for sex selection

15. Pre-implantation testing for selecting of the sex of an embryo is permissible, subject to the following conditions:

(a) Any fertility specialist receiving a request for pre-implantation sex selection must record in the Central Data Bank each live birth following pre-implantation sex selection.

(b) If after two years of the date of promulgation of these regulations there is evidence in the Central Data Bank of bias in favour of a particular sex to the extent that it would have a statistically significant impact on the sex ratio at population level if allowed to continue, the Minister of Health may place a moratorium on pre-implantation sex selection by notice in the Government Gazette for a period not exceeding five years.

Recipient files and availability of information

16. (1) A fertility specialist who effects the reproduction using ART must immediately record or file the following particulars and documents in a recipient file referred to in regulation 13(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 reproduction using ART, 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 reproduction using ART;

(e) the informed written consent contemplated in regulation 13(1)*(b)*;

(f) any other relevant document or information that the fertility specialist may obtain, including a document or information regarding previous reproduction using ART 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 contemplated in regulation 13(2);

(iii) the number of embryos in storage;

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

(v) the number of embryos destroyed.

(2) The competent person referred to in sub-regulation (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 reproduction using ART of the recipient, was effected,

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

(iv) the particulars contemplated in sub-regulation (1)*(g)*; and

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

Registry of authorised institutions and competent persons

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

(a) authorised institutions as contemplated in regulation 3, here reproduction using ART 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 registry 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 registry 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 registry 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 reproduction using ART 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 registry, 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 must-

(a) be entered in the registry; 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 registry and may not perform reproduction using ART.

Reporting of births by fertility specialist

18. (1) The fertility specialist who effected reproduction using ART must follow up with the mother and record such birth and information referred to in sub-regulation (2), within 30 days of such birth.

(2) The information which must be recorded in terms of sub-regulation (1) shall

include, but not be limited to-

(a) confirmation of birth;

(b) the unique identification number referred to in regulation 13(1)*(a)*; and

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

Reporting of disorders and mental illnesses by authorised institution

19. (1) Should it come to the attention of an authorised institution that effected reproduction using ART that a child born as a result of the reproduction using ART 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

20. No person must disclose the identity of any person who donated a gamete or received a gamete, or any matter related to the reproduction using ART of such gametes, or reproduction resulting from such reproduction using ART except where a law provides otherwise or a court so orders.

Appeals

21. (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 sub-regulation (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

22. 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

23. 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

24. These Regulations are called the REGULATIONS ON THE USE OF ASSISTED REPRODUCTIVE TECHNOLOGY, 2021.

_____

DR Z.L MKHIZE, MP
MINISTER OF HEALTH
DATE

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:

ACCREDITATION

ACCREDITATION:

STANDARDS: ISO, SABS? OR OTHERS

QUALITY MANAGEMENT SYSTEM:

TESTING LABORATORY ACCREDITED:

STORAGE SYSTEM: