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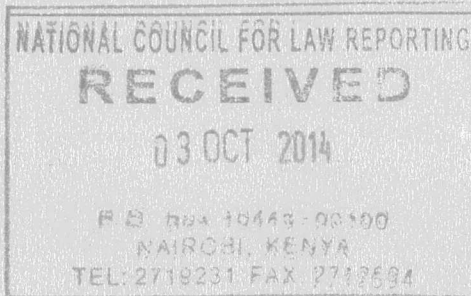
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**PROVISION AS TO THE CONDUCT OF BUSINESS AND
AFFAIRS FO THE AUTHORITY**

THE IN-VITRO FERTILIZATION BILL, 2014**A Bill for**

AN ACT of Parliament to for the regulation of In-vitro fertilization, to prohibit certain practices in connection with in-vitro fertilization, to establish an in-vitro fertilization Authority; to make provision in relation to children born of in-vitro fertilization process and for connected purposes

ENACTED by the Parliament of Kenya, as follows—

1. This Act may be cited as the In-Vitro Fertilization Act, 2014.

Short title

2. In this Act, unless the context otherwise requires—

Interpretation.

“Authority” means the Human Fertilization Authority established under Section 10;

“Cabinet Secretary” means the Cabinet Secretary for the time being responsible for health;

No. 17 of 2012.

“Director” means a person appointed as such under section 11;

“donor” means a person who voluntarily gives his or her gametes for the purpose of fertilization in an in vitro fertilization process and the person need not be the spouse of the person she or he is donating the gametes to;

“eggs” means live human eggs but do not include eggs in the process of fertilization;

“embryo” means a live human egg where fertilization is either in the process or complete;

“gametes” means a mature sperm or egg capable of fusing with a gamete of the opposite sex to produce the fertilized egg but does not include gametes in the process of fertilization;

“in vitro fertilization” means fertilization in a laboratory dish or test tube of sperm with eggs which have been obtained from an ovary, whether or not the process of fertilization is completed in the laboratory dish or test tube.

“primitive streak” means a primitive streak that develops in the early stages of human reproduction, that is to be taken to have appeared in any embryo not later than

the end of the period of 14 days beginning with the day when the gametes are mixed, not counting any time during which the embryo is stored and the presence of which signifies the creation of a unique human being;

“procreation” means the process of conceiving and delivering a baby, whether through a facilitated process or through natural means.

“sperm” means the male gametes produced in the testicles and contained in semen;

“surrogate mother” means a woman who has agreed to carry a pregnancy to term another woman under a surrogacy agreement and lays no legal claim to the born child.

“treatment services” for purposes of this Act, means medical, surgical or obstetric services provided to the public or a section of the public for the purpose of assisting women to carry children.

3. This Act applies to all processes of facilitated human fertilization undertaken outside the human body, whether or not the process is completed outside the human body.

Application.

PART II—ESTABLISHMENT, POWERS AND FUNCTIONS OF THE IN-VITRO HUMAN FERTILIZATION AUTHORITY

4. (1) There is established an Authority known as the In-Vitro Fertilization Authority.

Establishment of the Authority.

(2) The Authority shall be a body corporate, with perpetual succession and a common seal and shall be capable, in its corporate name, of-

- (a) suing and being sued;
- (b) taking, purchasing or otherwise acquiring, holding or disposing of movable or immovable property;
- (c) entering into contracts;
- (d) borrowing money; and
- (e) doing or performing all such other acts or thing necessary for the proper performance of its functions under this Act.

(3) The Authority may establish such branches or organs as it may deem necessary for the effective and proper discharge of its function under this Act.

5. The functions of the Authority shall be to—

Functions of the Authority.

- (a) develop standards, regulations and guidelines on in-vitro human fertilization;
- (b) advise the Cabinet Secretary on matters relating to the treatment and care of persons undergoing in-vitro fertilization and to advise on the relative priorities to be given to the implementation of specific measures in regard to in-vitro fertilization;
- (c) undertake research on the conduct, control and treatment of in-vitro fertilization;
- (d) develop programs for awareness creation on the methods of in-vitro fertilization treatment;
- (e) prescribe minimum requirements for the physical infrastructure for in-vitro fertilization clinics;
- (f) grant, vary, suspend and revoke licenses;
- (g) keep under review information about embryos and any subsequent development of embryos;
- (h) provide advice and information to persons receiving in-vitro fertilization treatment including persons providing gametes or embryos under this Act;
- (i) disseminate information to the public on reproductive health that may relate or affect in-vitro human fertilization;
- (j) establish and maintain a national database on persons receiving in-vitro fertilization treatment services or providing gametes or embryos for use;
- (k) perform such other functions as may be necessary for the better carrying out of the functions of the Authority under this Act.

6. (1) The Authority shall have all powers necessary for the proper performance of its functions under this Act.

Powers of the Authority.

(2) Without prejudice to the generality of the foregoing, the Authority shall have power to—

- (a) control, supervise and administer the assets of the Authority in such manner as best promotes the purpose for which the Authority is established;

- (b) receive any grants, gifts, donations or endowments and make legitimate disbursements there from;
- (c) levy fees for services rendered by the Authority as may be determined from time to time by the Board;
- (d) open such banking accounts for the funds of the Authority as may be necessary;
- (e) enter into association with such other bodies or organizations within or outside Kenya as it may consider desirable or appropriate in furtherance or for the performance of its functions under this Act;
- (f) perform or undertake any other activity that may be necessary for the fulfillment of any of the functions of the Authority under this Act.

7. The management of the Authority shall vest in a Board of the Authority which shall comprise of—

Board of the Authority.

- (a) a chairperson appointed by the President and approved by the National Assembly;
- (b) the Principal Secretary in the Ministry for the time being responsible for finance or a representative designated in writing by the Principal Secretary;
- (c) the Principal Secretary in the Ministry for the time being responsible for health or a representative designated in writing by the Principal Secretary;
- (d) six persons appointed by the Cabinet Secretary of whom—
 - (i) two shall be medical doctors, a woman and a man who possess proven knowledge and experience in reproductive health, nominated by the Kenya Medical Board;
 - (ii) two shall be lawyers, a woman and a man, who have actively contributed to the promotion of the rights and welfare of women and children nominated by the Law Society of Kenya;
 - (iii) one shall be a representative of the Kenya National Human Rights and Equality Commission; and
- (e) the Director of the Authority, who shall be the Secretary to the Board;

8. The Chairperson and the members of the Board appointed under paragraph (d) (i) (ii) and (iii) of section 7 shall hold office for a term of three years and shall be eligible for re-appointment for one further term of three years.

Term of office.

9. The conduct and regulation of the business and affairs of the Board shall be as provided in the First Schedule.

Conduct of business and affairs of the Authority.

10. The functions of the Board shall be to-

Functions of the Board.

- (a) formulate the policies of the Authority;
- (b) carry out the objects and functions of the Authority;
- (c) provide overall directions on effective coordination of the operations of the Authority; and
- (d) do anything incidental or conducive to the performance of any of the preceding functions.

11. (1) There shall be a Director of the Authority who shall be appointed by the Board upon such terms and conditions as the Board may determine.

Director of the Authority.

(2) The Director shall-

- (a) be an *ex-officio* member of the Authority but shall have no right to vote in any meeting of the Authority;
- (b) be the secretary to the Authority;
- (c) be responsible for the administration and day to day management of the affairs of the Authority;
- (d) ensure the maintenance of efficiency and discipline by all staff of the Authority; and
- (e) perform such other functions as may be assigned by Board

12. The Board may appoint such officers, agents and other staff as are necessary for the efficient discharge of its functions under this Act and upon such terms and conditions as the Board may determine

Staff of the Authority.

13. The Board may engage experts or consultants as it considers appropriate, to assist in the discharge of the functions of the Authority

Experts and consultants.

14. The Board shall pay its members and staff such remuneration or allowances as it may determine upon the advice of the Salaries and Remuneration Commission.

Remuneration of Board members and staff of the Authority.

15. The Board may, by resolution either generally or in any particular case, delegate to any committee of the Authority or to any officer, member of staff or agent of the Authority, the exercise of any of the powers or the performance of any of the functions or duties of the Authority under this Act.

Delegation by the Authority.

16. or by an officer, employee, agent or servant thereof shall, if the act or omission was done *bona fide* for the purposes of executing a function, power or duty under the Act, render such member, officer, employee, agent or servant personally liable to any action, claim or demand whatsoever.

Protection from personal liability.

(2) The provisions of subsection (1) shall not relieve the Authority of the liability to pay compensation or damages to any person for any injury to him, his property or any of his interests caused by the exercise of any power conferred by this Act or by any other written law or by the failure, whether wholly or partially, of any works.

17. (1) The common seal of the Authority shall be kept in such custody as the Authority may direct and shall not be used except on the order of the Authority.

The seal.

(2) Affixing of the common seal of the Authority shall be authenticated by the signature of the chairperson and the Director an any document not required by law to be made under seal and all decisions of the Authority may be authenticated by the signatures of the Chairperson and the Director

(3) Notwithstanding the provisions of subsection (2), the Authority shall, in the absence of either the Director or the chairperson in any particular matter, nominate a member to authenticate the seal of the Authority on behalf of either the chairperson or the Director.

(4) A deed, instrument, contract or other document executed in accordance with sub-section (2) shall bind the Authority.

PART III —PROHIBITED ACTIVITIES

18. (1) A person shall not, create, keep or use an embryo except as provided under this Act.

Use of embryo.

19. No person shall make use of any human reproductive material for the purpose of creating an embryo unless the donor of the material has given written consent, in accordance with the prescribed Regulations, to its use for that purpose.

Consent of parties.

20. No person shall remove a human reproductive material from the body of a donor after the death of the donor for the purpose of in-vitro fertilization unless the donor of the material has given written consent, in a manner prescribed by Regulations, to its removal for that purpose.

Posthumous use without consent.

21. (1) A person shall undertake in-vitro fertilization only for procreation purposes.

In-vitro human fertilization for procreation purposes.

22. (1) A person qualifies to undertake in-vitro fertilization, where it is certified by a medical doctor that-

Circumstances for undertaking in-vitro human fertilization.

(a) the person is due to factors related to age, having difficulties in conceiving naturally; and

(b) the person is due to factors related to lifestyle having difficulties in conceiving naturally.

(2) Except as provided under subsection (1), a person may qualify to undertake in-vitro fertilization, on any other medical, psychological or health grounds as may be determined by a medical doctor;

23. A person shall not undertake in-vitro fertilization for –

Circumstances under which in-vitro human fertilization is precluded.

(a) any purpose other than creating a human being ;

(b) experimental purposes aimed at modifying the human race ; or

(c) purely speculative purposes

24. A person shall not for purposes of in-vitro fertilization place in a woman –

Use of embryo in a woman.

(a) an embryo other than a human embryo; or

(b) a gamete other than a human gamete.

25. No person shall obtain a sperm or ovum from a donor under eighteen years of age, or use any sperm or ovum obtained from a donor under eighteen years of age except for the purpose of preserving the sperm or ovum or for the purpose of creating a human being that the person reasonably believes will be raised by the donor.

Gametes obtained from minor.

26. The Authority shall not issue a license that allows—
- (a) the keeping or using of an embryo other than a human embryo;
 - (b) the keeping or using of an embryo after the appearance of the primitive streak;
 - (c) the placing of a embryo in any animal;
 - (d) the keeping or using of an embryo in circumstances prohibited under this Act or as prescribed by Regulations.
 - (e) the replacing of a nucleus of a cell of an embryo with a nucleus taken from a cell of any person, embryo or subsequent development of an embryo; or
 - (f) any form of human cloning.

Authority not to issue license.

27. (1) A person shall not—

- (a) store or use any gametes save as provided under this Act;
- (b) in the course of providing in-vitro fertilization treatment services to a woman, use the sperm of any man unless the services are being provided for the woman and the man together and both parties have consented to the treatment;
- (c) in the course of providing in-vitro fertilization treatment services for a woman, use the egg of another woman without her consent;
- (d) mix human gametes with the live gametes of an animal; or
- (e) place sperms and eggs in a woman except in pursuance of a license as provided for under this Act.

PART IV—RIGHTS OF PARENTS, DONORS AND CHILDREN

28. (1) In this Act, unless the context otherwise requires—

Mother.

“mother” means a woman who is carrying or has carried a child as a result of placing in her an embryo or sperm and eggs or artificial insemination of the woman

under a process of assisted reproduction as provided under this Act and shall not include a woman carrying a child under a surrogate motherhood agreement.

“father” means a person who, in the case of a child who is being carried or has been carried by a woman as a result of placing in the woman an embryo or sperm and eggs or the artificial insemination of the woman, if –

- (a) the person donated his sperms for the process of in-vitro fertilization ; and at the time of placing in the woman the embryo or the sperm and eggs or artificial insemination of the woman, the woman was party to a marriage with the person;
- (b) at the time of placing in the woman of the embryo or the sperm and eggs or artificial insemination of the woman, the woman was not party to a marriage with the person but has subsequently married the person; or
- (c) at the time of placing in the woman the embryo or the sperm and the eggs or of the woman, the woman was not party to a marriage with the person and has not subsequently married the person, but the person has, with approval of the mother, written a parental agreement acquiring the rights of fatherhood to the child.

(2) If at the time of placing in a woman the embryo or the sperm and eggs or artificial insemination of the woman, the woman was a party to a marriage, and the creation of the embryo carried by the woman was not brought about with the sperm of the other party to the marriage, the party to the marriage shall, with the consent of the other party to the marriage, be considered a father;

(3) A child who is adopted belongs to the person or persons who adopted the child.

29. Where the sperm of a man, or any embryo the creation of which was brought about with the sperm of the man was used after the death of the man, the man shall not be treated as the father of the child unless-

- (a) the mother was married to the man at the time of the death of the man and the insemination takes place within one year of the death of the man; and

Use of sperm
after the death of
a man.

- (b) the man had consented to parentage and the artificial insemination takes place within one year of the death of the man.

30. The parties to a marriage under section 28 –

Parties to a marriage.

- (a) are parties to a marriage recognized under any of the systems of laws in Kenya, and subsisting at that time;
- (b) include parties to a void marriage if either or both of the parties reasonably believed at that time that the marriage was valid;
- (c) include parties who have been cohabiting together as man and wife for a period or periods totaling to at least two years;
- (d) applies whether the woman was in Kenya or elsewhere at the time of the placing in the woman an embryo or sperm and eggs or her artificial insemination.

31. A child born out of in-vitro fertilization under this Act shall have the same legal rights under the Constitution or any other written law as that of a child born through sexual intercourse.

Rights to accrue to child.

32. (1) A woman of not less than eighteen years may, at the request of any two persons, male and female have an embryo or sperm and eggs of the two persons, male and female placed or artificially inseminated in her for purposes of surrogate motherhood.

Surrogate motherhood.

(2) The surrogate mother under subsection (1) shall carry the child on behalf of the two persons and shall relinquish all parental rights over the child unless a contrary intention is proved.

33. (1) In this section-

- “parties to a marriage” mean husband and wife;
- “court” means the High Court of Kenya;

Parental orders in favor of gamete donors.

(2) The Court may make an order providing for a child to be treated in law as the child of the parties to a marriage if-

- (a) the child has been carried by a woman other than the wife as result of placing in the woman of an

embryo or sperm and eggs or artificial insemination of the woman;

- (b) the gametes of the husband or wife, or both, were used to bring about the creation of the embryo, and
 - (c) the conditions in subsections (3), (4), (5) (6) and (9) are satisfied.
- (3) A husband and a wife shall, sign a surrogacy agreement, before the placing in a woman of an embryo or sperm and eggs or artificial insemination of the woman.

(4) The husband and the wife must apply for the parental order within one year of the birth of the child or, in the case of a child born before the coming into effect of this Act, within one year of such coming into force.

(5) A husband, wife or both must be domiciled in Kenya at the time of the application, and of the making of the order under subsection (4),

(6) At the time of making of an order, both the husband and the wife must have attained the age of eighteen.

(7) The Court must be satisfied that any person who is a father of a child by virtue of section 7 (b), has freely and with full understanding of what is involved agreed unconditionally to the making of the order.

(8) A person under subsection (7) shall not require the agreement of a person who cannot be found or is incapable of giving agreement.

(9) The court must be satisfied that no money or other benefits other than for expenses reasonably incurred has been given or received by the husband or the wife for or in consideration of—

- (a) the making of the order;
- (b) any agreement required under subsection (7); and
- (c) the making of any arrangements with a view to making the order, unless authorized by the court.

PART V— ACCESS TO INFORMATION

34. (1) The Authority shall keep and maintain a register containing particulars on—

In-vitro
fertilization
Register.

- (a) the in-vitro fertilization treatment services provided to persons;
- (b) the keeping or use of gametes of persons or of an embryo taken from any particular woman, or
- (c) persons who undergo in-vitro fertilization;
- (d) donors of embryos and gametes; and
- (e) persons conceived in consequence of in-vitro fertilization treatment services.

35. (1) A person who has attained the age of eighteen may by notice to the Authority require the Authority to-

Provision of information by the Authority.

- (a) provide information stating whether or not the information contained in the register shows that a person other than a parent of the applicant may be a parent of the applicant.
- (b) avail information on whether the applicant was conceived by means of in-vitro fertilization; and
- (c) state whether or not the information contained in the register shows that the applicant, and a person specified in the request as a person whom the applicant proposes to marry would or might be relatives.

(2) The Authority shall comply with the request of the applicant made under section 35 if-

- (a) the information contained in the register shows that the person was, or may have been, born in consequence of in- vitro fertilization treatment services, and
- (b) the person has been given an opportunity to receive counseling in regard to the implications of compliance with the request.

(6) The Authority shall not give information regarding the identity of a person whose gametes have been used or from whom an embryo has been taken if a person to whom a license applied was provided with the information at a time when the Authority was not required to give the information.

36. (1) The Authority shall not avail information to a person below the age of eighteen years unless the information is necessary for a medical procedure relating to the minor.

Minor not to be given information.

(2) Where a minor seeks such information, the minor may, through a legal guardian, give notice to the Authority requesting the Authority to give the information and the Authority shall give the information, if –

- (a) the information contained in the register shows that the minor was, or may have been, born in consequence of in-vitro fertilization treatment services, and
- (b) the minor has been given an opportunity to receive counseling on the implications of compliance with the request.

37. (1) Where a government agency makes a claim to the Authority seeking to verify whether a man is or is not the father of a child and the Authority shall comply with the request made by the government agency unless it appears to the Authority that there is not sufficient reason to seek for that information.

Information from the Authority.

(2) Where the government agency is aggrieved by the decision of the Authority, the agency may appeal to the Court for determination of the matter.

38. (1) A person who is or has been a member or employee of the Authority shall not disclose any information which the person holds or has held as a member or employee of the Authority.

Restriction on disclosure of information.

(2) The information specified under subsection (1) is —

- (a) information contained in the register kept pursuant to section 34 of this Act; and
- (b) any other information obtained by any member or employee of the Authority on terms or circumstances requiring it to be held in confidence.

(3) Subsection (1) does not apply to disclosure of information specified under subsection (2) (a) made —

- (a) to a person as a member or employee of the Authority;
- (b) to a person to whom a license applies for the purposes of the functions under this Act;
- (c) with the consent of a person or persons whose confidence would otherwise be protected;

- (d) in pursuance of an order of a court under this Act;
- (e) to any government agency in pursuance of a request under section 37 of this Act, or
- (f) made lawfully available to the public before the disclosure is made.

PART VI— LICENSING

39. (1) The Authority shall, in accordance with this Act issue, vary, revoke or renew a licence in relation to activities under this Act. License.

40. No person shall carry out in-vitro fertilization unless the person is issued with a valid license under this Act. Requirement for licence.

41. (1) An application for a licence under this section shall be made to the Authority in duplicate, signed by the applicant, specifying his name and place of business. Application for licence.

(2) Every application under this section shall be accompanied by the prescribed fee.

(3) Where an application is made by a person in accordance with this section, the Authority shall issue the person a license to carry out in-vitro fertilization , if satisfied that the person meets such other requirement as may be prescribed, and if not satisfied, shall refuse the application

42. (1) The Authority shall, before considering an application authorizing a person to carry out in-vitro fertilization on premises, arrange for the premises where in-vitro fertilization process is to be carried on to be inspected, and a report made regarding the inspection. Inspection of premises before license is issued.

(2) Subject to subsection 3, the Authority shall inspect once in each calendar year, any premises where in-vitro fertilization is to be carried and a report made on the inspection.

(3) The Authority may not inspect a premise in any particular year if the Authority considers the inspection in that year unnecessary.

43. (1) The Authority may, in accordance with this Act, attach conditions to a license . General conditions for licenses.

(2) The conditions specified under subsection (1) are that—

- (a) the activities authorized by the license shall be carried on only on the premises to which the license relates and under the supervision of the person responsible;
- (b) any member or employee of the Authority, shall upon identification be permitted, at all reasonable times to enter premises to which the license relates and inspect the premises including the inspection of any equipment, records and observing any activity;
- (c) proper records shall be maintained in such form as the Authority may direct;
- (d) no money or other benefit shall be given or received in respect of any supply of gametes or embryos unless authorized by the Authority;
- (e) where gametes or embryos are supplied to a person to whom another license applies, the person shall be provided with information as may be specified by the Authority; and
- (f) the Authority shall be provided with copies or extracts from the records or information, in such form and at such intervals as it may specify.

(3) Every licensee shall keep and provide information to the Authority and any government bodies on—

- (a) the persons to whom in-vitro fertilization services are provided;
- (b) the kind of in-vitro fertilization services provided;
- (c) the persons whose gametes are kept or used for the purposes of in-vitro fertilization services
- (d) the persons whose gametes have been used in bringing about the creation of embryos.
- (e) such other matters as the Authority may specify.

(4) No information shall be removed from any records maintained in pursuance of a license before the expiry of a period specified by the Authority.

(5) A woman shall not be provided with any treatment services that involve—

- (a) the use of any gametes of any person, if the consent of the person is required under this Act and the consent has not been obtained;
- (b) the use of any embryo taken from another woman, if the consent of the woman from whom it was taken has not been obtained
- (c) the procedures specified under paragraph (a) and (b) , unless the woman has been provided with relevant information and given an opportunity to receive counseling on the implications of taking the proposed steps.

44. (1) Every license authorizing the storage of gametes or embryos shall have the condition that-

Conditions for storage of gametes.

- (a) the gametes of a person or an embryo taken from a woman shall be placed in storage only if received from that person or woman or acquired from a person to whom a license applies;
- (b) an embryo the creation of which has been brought about by in vitro than in pursuance of the license shall be placed in storage only if acquired from a person to whom the license applies;
- (c) gametes or embryos which are stored shall not be supplied to a person other than in the course of providing treatment services unless that person is a person to whom a license applies;
- (d) no gametes or embryos shall be kept in storage for longer than the statutory storage period, and
- (e) information regarding persons whose consent is required under this Act, the terms of their consent and the circumstances of the storage and as to such other matters as the Authority may specify shall be included in the records maintained in pursuance of the license.

(3) The storage period in respect of embryos shall be a period not exceeding five years or as the license may specify.

45. Where an application for a license is made to the Authority the Authority shall issue the person a license if satisfied that —

Grant of License.

- (a) the application is for a license designating the applicant as the person under whose supervision the activities to be authorized by the license are to be carried on;
- (b) either the person is the applicant or -
 - (i) the application is made with the consent of the person; and
 - (ii) the applicant is a suitable person to hold a license.
- (c) the character, qualifications and experience of the person making the application are such as are required for the supervision of the activities under this Act and that the person is qualified to discharge the duties under this Act;
- (d) the premises in respect of which the licence is to be granted are suitable for the activities, and
- (e) all other requirements under this Act in relation to granting of a licence are satisfied.

(3) The Authority may grant a licence to any person by way of renewal whether on the same or different terms.

(4) Where the Authority is of the opinion that the information provided in the application is insufficient to enable it to determine the application, the Authority shall not consider the application until the applicant has provided further information as the Authority may require.

(5) The Authority shall not grant a license unless a copy of the conditions to be imposed by the licence have been provided to, and acknowledged in writing by the applicant and the person under whose supervision the activities are to be carried on.

(6) The fee specified under subsection (1) means a fee of such amount as may be fixed from time to time by the Authority with the approval of the Cabinet Secretary.

(7) In determining the amount of fee under subsection (6), the Authority may have regard to the costs of performing all its functions.

(8) The Authority may fix different fees for different circumstances and any fees paid under this section shall not refundable.

46. (1) It shall be the responsibility of the person under whose supervision the activities authorized by a licence are carried on to ensure –

Responsibility of the supervisor.

- (a) that the persons to whom the licence applies are of such character, and are qualified by training and experience, to be suitable persons to participate in the activities authorized by the licence;
- (b) that proper equipment is used;
- (c) that proper keeping of gametes and embryos and for the disposal of gamete or embryos that have been allowed to perish; and
- (d) that the conditions of the licence are complied with.

(2) The persons to whom a licence applies under this Act are –

- (a) persons under whose supervision the activities authorized by a licence are carried on
- (b) any person designated in the licence, or in a notice given to the Authority by the person who holds the licence or the person responsible, as a person to whom the licence applies, and
- (c) any person acting under the direction of the person responsible or of any person designated .

47. (1) The Authority may revoke a license if satisfied –

Revocation of licence.

- (a) that the information given for the purposes of the application for the grant of the licence was false or misleading;
- (b) that the premises to which the licence relates are no longer suitable for the activities authorized by the licence;
- (c) that the person responsible has failed to discharge, or is unable because of incapacity to discharge, the duty under this Act or has failed to comply with directions given in connection with any licence;
- (d) that there has been a change of circumstances since the licence was granted;

- (e) that the character of the person responsible is not as is required for the supervision of the activities or that the nominal licensee is a suitable person to hold a licence; or
- (f) the person responsible dies or is convicted of an offence under this Act.

(2) Where the Authority has power to revoke a license under subsection (1), the Authority may vary any terms of the licence.

(3) The Authority may, on application by the person responsible or the nominal licensee, vary or revoke the licence.

(4) The Authority may, on an application by the nominal licensee, vary the licence so as to designate another person in place of the person under whom supervision is authorized by a licence, if the Authority is satisfied that the character, qualifications and experience of the other person are such as are required for the supervision of the activities authorized by the licence and that the person shall discharge the duties under this Act, and the application is made with the consent of the other person.

(5) Except on an application under subsection (4), the Authority may vary a licence under this section –

- (a) if it relates to the activities authorized by the licence, the manner in which they are conducted or the conditions of the licence, or
- (b) so as to extend or restrict the premises to which the licence relates.

(6) The Cabinet Secretary shall make Regulations for the refusal, variation and revocation of licenses by the Authority under this Act.

48. (1) Where the Authority refuses issue a licence or refuses to vary a licence—

Appeal to the Authority.

- (a) the applicant may appeal to the Authority within 30 days of the date on which the decision was served on the applicant; and
- (b) the Authority may make such determination on the appeal as it thinks fit.

(2) The Authority shall give notice of its decision to the appelland and, if it is a decision to refuse a licence or to refuse to vary a licence so as to designate another person in place of the person under whom supervision is authorized by a licence, or a decision to vary or revoke a licence, shall include in the notice the reasons for the decision.

(3)The functions of the Authority on an appeal under this section cannot be discharged by any committee, member or employee of the Authority and, for the purposes of the appeal the quorum shall not be less than five.

49. Where the Authority determines under section 48 of this Act —

Appeal to the High Court.

- (a) to refuse a licence or refuse to vary a licence so as to designate another individual in place of the person under whom supervision is authorized by a licence,; or
- (b) to vary or revoke a licence;

the person on whom notice of the determination was served may appeal to the High Court.

50. (1) Where the Authority -

Temporary suspension of a licence.

- (a) has reasonable grounds to suspect that there are grounds for revoking the licence for non-compliance with this Act, and
- is of the opinion that the licence should immediately be suspended

the Authority may by notice suspend the licence for a period not exceeding three months.

(2) The Authority shall give notice under subsection (1) to the person under whom supervision is authorized by a licence or, where the person under whom supervision is authorized by a licence is dead or appears to the Authority to be unable because of incapacity to discharge the duty imposed on him under this Act, to some other person to whom the licence applies or the nominal licensee and the Authority may, by a further notice to that person, renew or further renew the notice under subsection (1) specified in the renewal notice.

PART VII – FINANCIAL PROVISIONS

51. The funds of the Authority shall consist of—

Funds of the Authority.

- (a) such monies or assets as may accrue to the Authority in the course of the exercise of its powers or the performance of its functions under this Act;
- (b) gifts, grants or donations as may be given to the Authority;
- (c) monies that may be borrowed by the Board of Management for the discharge of the functions of the Authority;
- (d) monies from any other source provided for the Authority.

52. The Financial year of the Authority shall be the period of twelve months ending on the thirtieth day of June in each year.

Financial year.

53. (1) At least three months before the commencement of each financial year, the Authority shall cause to be prepared estimates of the revenue and expenditure of the Authority of that year

Annual Estimates

(2) The annual estimates shall make provisions for all estimated expenditure of the Authority for the financial year concerned and in particular, shall provide for-

- (a) the payment of the salaries, allowances and other charges in respect of the staff of the Authority;
- (b) the payment of pensions, gratuities and other charges in respect of benefits which are payable out of the funds of the Authority;
- (c) the acquisition and maintenance of the buildings and grounds of the Authority;
- (d) the funding of training, research and development activities of the Authority;
- (e) the proper maintenance, repair and replacement of any installation and of the equipment and other movable property of the Authority;
- (f) the creation of such funds to meet future or contingent liabilities in respect of benefits, insurance or replacement of buildings or installation or equipment and in respect of such other matters as the Authority may think fit.

(3) The annual estimates shall be approved by the Authority before the commencement of the financial year to which they relate, and shall be submitted to the Cabinet Secretary for approval and after the Cabinet Secretary has given approval, the Authority shall not increase any sum provided in the estimates without written consent of the Cabinet Secretary.

(4) No expenditure shall be incurred for the purposes of the Authority except in accordance with the annual estimates approved under subsection (3), or in pursuance of an authorization of the Authority given with the prior approval of the Cabinet Secretary.

54. (1) The Authority shall cause to be kept all proper books and records or account of the income, expenditure, assets and liabilities of the Authority.

Accounts and
Audit.

(2) The Cabinet Secretary for the time being responsible for finance may prescribe the form of any book required to be kept under subsection (1) and unless a form has been prescribed, a form suitable for the purpose shall be used.

(3) Within a period of three months after the end of each financial year, the Authority shall submit to the Controller and Auditor General the accounts of the Authority in respect of that year together with—

- (a) a statement of the income and expenditure of the Authority during the financial year;
- (b) a statement of the assets and liabilities of the Authority on the last day of that financial year.

(4) The accounts of the Authority shall be audited and reported upon by the Controller and Auditor – General in accordance with the provisions of the Public Audit Act, 2003.

55. (1) The Authority may invest any of its funds in securities in which for the time being trustees may by law invest trust funds or in any other securities which the Treasury may, from time to time approve.

Investments of
Funds.

(2) The Authority may place on deposit with such bank or banks or financial institutions as it may determine, any moneys not immediately required of the purposes of the Authority.

56. (1) The Authority shall cause an annual report to be prepared for each financial year. Annual Reports.

(2) The Authority shall submit the annual report to the Cabinet Secretary within three months after the end of the year to which it relates;

(3) The annual report shall contain, in respect of the year to which it relates-

- (a) the financial statements of the Authority;
- (b) a description of the activities of the Authority;
- (c) such other statistical information as the Authority considers appropriate relating to the work of the Authority;
- (d) any other information relating to the functions that the Authority considers necessary.

(4) The Cabinet Secretary shall, within thirty days, after receiving the annual report, transmit it to the National Assembly.

57. The Authority may, any time, submit a special report to the National Assembly through the Cabinet Secretary with respect to any aspect of the functions of the Authority which the Authority considers should, in the national interest, be brought to the attention of the National Assembly. Special reports.

PART VIII – MISCELLANEOUS PROVISIONS

58. (1) A person commits an offence under this Act where the person knowingly or recklessly- Offences.

- (a) contravenes any of the provisions of the Act;
- (b) contravenes any of the provisions of a notice issued under this Act; or
- (c) obstructs a person in the execution of the person's duty under the Act.

(2) A person who commits an offence under subsection Shall, upon conviction, be liable to a fine not exceeding five hundred thousand shilling or to a term not exceeding five years, or to both.

59. Any person convicted of an offence under this Act General penalty. for which no penalty is provided shall be liable to a fine not

exceeding one hundred thousand shillings or to imprisonment for a term not exceeding two years, or to both.

PART IX—PROVISIONS ON DELEGATED POWERS

60. The Cabinet Secretary may, make regulations generally for the better carrying out of the provisions of this Act, and without prejudice to the generality of the foregoing, may make regulations —

Regulations.

- (a) for the eligibility of donors;
- (b) for the storage of gametes and embryos;
- (c) for the number of embryos that can be planted in a woman;
- (d) for the number of times that a patient can be given in vitro fertilization a procedure;
- (e) for settling disputes arising out of in vitro fertilization;
- (f) for the maintenance for records;
- (g) regarding rights and duties of patients, donors surrogates and children;
- (h) in respect of the giving of consent for the use of human reproductive material or an in vitro embryo or for the removal of human reproductive material;
- (i) in respect of the number of children that may be created from the gametes of one donor through the application of assisted reproduction procedures;
- (j) in respect of the terms and conditions of licenses;
- (k) in respect of the qualifications for licenses.
- (l) in respect of the issuance, amendment, renewal, in respect of suspension, restoration and revocation of licenses;
- (m) in respect of the information to be provided in respect of applications for a license or for the renewal or amendment of a license;
- (n) in respect of the identification and labeling of human reproductive materials and in vitro embryos used in treatment services;
- (o) in respect of the collection, use and disclosure of information regarding in-vitro fertilization;

(p) in respect of counseling services;

SCHEDULE (S.9)

PROVISIONS AS TO THE CONDUCT OF BUSINESS AFFAIRS OF THE BOARD

1. (1) A member appointed to the Board under paragraphs (a) and (e) of section 5 shall cease to be a member if the member-

Vacation of office.

- (a) serves the Cabinet Secretary with written notice of resignation;
- (b) is absent without written permission of the chairperson notified to the Board, from three consecutive meetings of the Board;
- (c) is convicted of a criminal offence and is sentenced to imprisonment for a term exceeding six months with or without the option of a fine; or
- (d) is incapacitated by prolonged physical or mental illness from performing the duties of the office of a member of the Board.

2. (1) The Board shall hold such number of meetings at such places and at such times as the Board shall consider necessary for the proper discharge of its functions.

Meeting of the Authority.

(2) Notwithstanding sub-paragraph (1) the Board shall meet not less than four times in each financial year.

(3) At least a fourteen days notice shall be given prior to any meeting of the Board

Special Meeting.

3. The chairperson or any three members may call a special meeting whenever it is expedient for the transaction of the business of the Board by giving not less than seven days notice to the members.

Presiding at meetings.

4. (1) The chairperson shall preside at all meetings of the Board

(2) In the absence of the chairperson at a meeting, the vice-chairperson shall preside at that meeting of the Board.

(3) In the absence of the chairperson and the vice-chairperson at a meeting, the members present shall elect a member to preside at that meeting off the Board

5. The quorum for the conduct of business at a meeting of the Board shall be the majority of the members or the Board.

Quorums.

6. (1) A decision on any matter before the Board shall be by a majority of votes of the members present and voting.

Voting.

(2) in case of an equality of votes, the chairperson or the person presiding shall have a casting vote

7. Proceedings of the Board shall not be invalid by reason only of a vacancy in the membership of the Board or by reason of a defect in the appointment of a member.

Vacancies and defects in appointment.

8. be kept in such a manner as the Board directs, and, on the written request of the Minister, shall be made available to him or any person nominated by him.

Minutes.

9. The Board may establish such committees as may be necessary for the performance of the functions of the Board.

Committees of the Authority.

10. Subject to the provisions of the Schedule, the Board shall regulate its own procedure.

Powers of the Authority to regulate its own procedure.
Code of conduct.

11. Within six months of the commencement of this Act, the Board shall establish a code of conduct for the practice and conduct of in-vitro fertilization.

12. (1) If a member of the Board is directly or indirectly interested in a contract or other matter before the Board and is present at a meeting of the Board at which the contract, proposed contract or other matter is the subject of consideration, that member shall, as soon as is practicable after the commencement of that meeting, disclose the fact.

Disclosure of interest.

13. The Director shall keep a record of all proceedings and meetings of the Board

Records.

MEMORANDUM OF OBJECTS AND REASONS

The Principal object of this Bill is to anchor the existence and practice of in vitro-fertilization in statute law. While it is acknowledged that infertility affects a lot of women of reproductive age in Kenya and in vitro fertilization is often a couple's or individual's only chance at conception there has never been an attempt to clothe the practice of in vitro-fertilization in a fine statutory line. It is imperative to note that many women who require in vitro-fertilization rely on doctors who may not be qualified to undertake the procedure and as a result leading to the deaths of many women and children.

The entire legal framework does not provide any substantive and procedural essentials for in vitro fertilization; most of the Acts that relate to health care for example the Medical Practitioners and Dentist Act (Cap.253) and the Medical Laboratory and Technologists Act (No. 10 of 1999) are silent on this fundamental matter. The result therefore is that the practice in in vitro fertilization which is very crucial to this country goes about in a state of virtual legal nudity.

This Bill therefore seeks to address these challenges and thereby empower and strengthen the practice of doctors in the area of in vitro fertilization. This will not only enhance the in vitro fertilization surveillance but also strengthen control and avoid losses.

Further, the Bill makes provisions that address not only the legal voids but also the likely societal concerns e.g. the consents necessary before undergoing in vitro-fertilization, regulation of the handling of embryos resulting from the in vitro-fertilization processes, protection of the identity, status and welfare of children borne as a result of in vitro

fertilisation, obligations of persons seeking to undertake the human vitro-fertilisation and their status as parents upon obtaining children through the process .

Significantly, the Bill creates an In vitro Fertilization Authority to regulate the processes of human vitro-fertilisation and in particular to develop standards, regulations and guidelines on in-vitro human fertilization, to undertake research on the conduct, control and treatment of in-vitro fertilization, to grant, vary, suspend and revoke licenses to provide advice and information to persons receiving in-vitro fertilization treatment including persons providing gametes or embryos and prescribe minimum requirements for the physical infrastructure for in-vitro fertilization clinics among others.

Countries which have designed a legal framework on human reproductive technologies have had to deal with a number of weighty and somewhat controversial issues. These include the appropriate balance

between legislation, regulation and reproductive freedom/liberty, the interplay between ethics and legislative intervention in human reproduction, keeping the law abreast with continuous and tremendous advancement in modern science and technology.

Examples of the Countries with legal frameworks for this area are Australia, UK, and South Africa among others.

Modern human reproductive technologies continue to evoke significant and often emotive ethical and scientific debate. More importantly, these technologies have brought novel legal challenges, particularly in the areas of marital relations, reproductive liberty, reproductive privacy, child rights and parental rights and responsibility.

Unfortunately, the Kenyan legal system lacks laws for the regulation of modern human reproduction technologies. The stark reality is that Kenyans continue to enter into arrangements involving modern reproductive technologies in spite of the absence of a legal regime for their regulation. This Bill therefore responds to the obvious need for a legal framework for regulation of human reproductive technologies and in particular, Vitro-fertilization in humans.

Even though decisions touching on reproduction and copulation fall within the private domain of individuals, there are formidable arguments in favour of legislative control on assisted reproduction. First, it is beyond debate that the state has a legitimate interest in restricting regulating reproductive freedom if there is demonstrable harm or negative impacts on society. Also, due to reliance on technology in assisted reproduction, the state has a legitimate interest in ensuring high standards of treatment, with a view to enhancing safety and protecting individuals from exposure to high levels of risk. Furthermore, the intervention of a third party in assisted reproduction (i.e. a doctor or clinic) removes the matter from private domain to public domain, warranting legislative intervention.

Therefore by enacting this Bill, the country would be taking a lead in helping couples who are not able to have children due to fertility problems conceive through in vitro fertilization.

PART I of the Bill contains preliminary provisions

PART II of the Bill provides for establishment of the In-Vitro Fertilization Authority with general mandate to regulate in vitro-fertilization processes in accordance with the Act;

PART III of the Bill provides for prohibited activities under this Act.

PART IV of the Bill provides for the rights of parents donors, and children.

PART V of the Bill provides for access to information.

PART VI of the Bill provides for licensing

PART VII of the Bill provides for financial provisions

PART VIII of the Bill provides for miscellaneous provisions

PART IX of the Bill provides for provisions on delegated powers

PROVISIONS ON DELEGATED POWERS

This law when enacted will confer on a number of bodies and persons authority to make provisions having the force of law in Kenya in terms of Article 94 (6) of the Constitution of Kenya, 2010.

The Cabinet Secretary for instance is given authority by section 60 of this Act to make Regulations. The purpose and objectives of making these regulations include the following:

- (a) to provide for the eligibility of donors;
- (b) to provide mechanisms for storage of gametes and embryos;
- (c) to determine the number of embryos that can be planted in a woman;
- (d) to provide for the number of times that a patient can be given in vitro fertilization a procedure; and
- (e) to establish mechanisms for settling disputes arising out of in vitro fertilization;

Limits of the Delegated Authority

The regulations made under this Act by the Cabinet Secretary will be limited to bringing into effect provisions of this Act and will therefore facilitate the promotion of public awareness control and management of in vitro fertilization.

The enactment of this Bill shall not occasion additional expenditure of public funds.

Dated 16th August, 2014.

MILLIE ODHIAMBO MABONA,
Member of Parliament.