

A BILL

FOR

AN ACT TO PROVIDE FOR A NATIONAL FRAMEWORK FOR THE
REGULATION AND SUPERVISION OF REPRODUCTIVE TECHNOLOGY AND
MATTERS CONNECTED THEREWITH

Sponsored by Senator Lanre Tejuoso

[] Commencement

ENACTED by the National Assembly of the Federal Republic of
Nigeria as follows:

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CHAPTER I - PRELIMINARY

1.-(1) This Bill may be cited as the Assisted Reproductive
Technology (Regulation) Bill, 2016.

Short Title

2. In this Act, and in any rules and regulations framed hereunder,
unless the context otherwise requires:

Definitions

(a) "artificial insemination", means the procedure of artificially
transferring semen into the reproductive system of a woman and includes
insemination with the husband's semen or with donor semen;

(b) "assisted reproductive technology", with its grammatical
variations and cognate expressions, means all techniques that attempt to
obtain a pregnancy by handling or manipulating the sperm or the oocyte
outside the human body, and transferring the gamete or the embryo into the
uterus;

(c) "assisted reproductive technology clinic", means any premises
used for procedures related to assisted reproductive technology;

(d) "child", means any individual, of whatever age, born through
the use of assisted reproductive technology;

(e) "couple", means the persons living together and having a sexual
relationship that is legal in the country / countries of which they are citizens
or they are living in;

1 (f) "cryo-preservation", means the freezing and storing of gametes,
2 zygotes and embryos;

3 (g) "donor", means the donor of a gamete or gametes but does not
4 include the husband who provides the sperm or the wife who provides the
5 oocyte to be used in the process of assisted reproduction for their own use;

6 (h) "embryo", means the fertilized ovum that has begun cellular
7 division and continued development up to the blastocyst stage till the end of
8 five days;

9 (i) "fertilization", means the penetration of the ovum by the
10 spermatozoon and fusion of genetic materials resulting in the development of a
11 zygote;

12 (j) "foetus", means the product of conception, starting from
13 completion of embryonic development until birth or abortion;

14 (k) "gamete", means sperm and oocyte;

15 (l) "gamete donor", means a person who provides sperm or oocyte
16 with the objective of enabling an infertile couple to have a child;

17 (m) "Nigerian Council of Medical Research", means the Nigerian
18 Council of Medical Research as registered under the Societies Registration
19 Act, 1860;

20 (n) "implantation", means the attachment and subsequent penetration
21 by the zona-free blastocyst, which starts five to seven days following
22 fertilization;

23 (o) "infertility", means the inability to conceive after at least one year
24 of unprotected coitus;

25 (p) "oocyte" and "ovum", mean, respectively, the female gamete
26 present in the ovary, and an ovulated oocyte in which the first polar body has
27 been released;

28 (q) "Pre-implantation Genetic Diagnosis", includes the technique in
29 which an embryo formed through in-vitro fertilisation is tested for specific
30 disorders prior to the transfer;

1 (r) "semen bank", shall be deemed to include both sperm and
2 oocytes;

3 (s) "sperm", means the male gametes produced in the testicles and
4 contained in semen ejaculated by a male;

5 (t) "surrogacy", means an arrangement in which a woman agrees to
6 a pregnancy, achieved through assisted reproductive technology, in which
7 neither of the gametes belong to her or her husband, with the intention to
8 carry it to term and hand over the child to the person or persons for whom she
9 is acting as a surrogate;

10 (u) "surrogate mother", means a woman who agrees to have an
11 embryo generated from the sperm of a man who is not her husband and the
12 oocyte of another woman, implanted in her to carry the pregnancy to full
13 term and deliver the child to its biological parent(s);

14 (v) "surrogacy agreement", means a contract between the person(s)
15 availing of assisted reproductive technology and the surrogate mother;

16 (w) "unmarried couple", means a man and a woman, both of
17 marriageable age, living together with mutual consent but without getting
18 married;

19 (x) "zygote", means the fertilized oocyte prior to the first cell
20 division.

21 CHAPTER II - CONSTITUTION OF AUTHORITIES TO REGULATE ASSISTED
22 REPRODUCTIVE TECHNOLOGY

23 3.-(1) There is hereby established a Board to be known as the
24 National Advisory Board for Assisted Reproductive Technology, hereafter
25 referred to as the National Board, to exercise the jurisdiction and powers and
26 discharge the functions and duties conferred or imposed on the Board by or
27 under this Act.

28 (2) The National Board shall consist of such number of members,
29 not exceeding twenty one, to be appointed by the President on the
30 recommendation of the Minister, as follows-

Establishment of
National Advisory
Board

- 1 (a) A Chairman to be appointed by the Ministry of Health;
- 2 (b) An officer, not below the rank of a Director from the Medical
3 Research Council, who shall be the Member- Secretary of this Board;
- 4 (c) A representative, not below the rank of a Director, from the
5 Ministry of Health ;
- 6 (d) The nominee of a professional society concerned primarily with
7 assisted reproduction;
- 8 (e) Up to sixteen other experts - of whom one each shall be a nominee
9 of the Ministry of Health and Medical Research Council, and at least six of
10 whom shall be women - in the fields of assisted reproduction, gynaecology,
11 embryology, andrology, bioethics, mammalian reproduction, medical
12 genetics, social science, law, or human rights, to be nominated by the Federal
13 Government.

14 (3) The Chairman of National Board shall nominate a Vice Chairman
15 from among its members.

Meetings of
National Advisory
Board

16 4.-(1) The National Board shall meet as and when necessary, not less
17 than two times a year, and at such time and place in the country as the
18 Chairperson of the National Board may think fit.

19 (2) The Chairperson of the National Board shall preside over the
20 meetings of the National Board.

21 (3) If, for any reason, the Chairperson of the National Board is unable
22 to attend any meeting of the National Board, the Vice-Chairperson of the
23 National Board shall preside over the meeting.

Functions of
National Advisory
Board

24 5.-(1) The National Board may recommend modification from time to
25 time in the attached rules and schedules where relevant in regard to the
26 following, and perform any other functions and tasks assigned to it by the
27 Federal Government:

28 (a) minimum requirements related to staff and physical infrastructure
29 for the various categories of assisted reproductive technology clinics;

30 (b) regulations in respect of permissible assisted reproductive

1 technology procedures;

2 (c) regulations in respect of selection of patients for assisted
3 reproductive technology procedures;

4 (d) encouragement and promotion of training and research in the
5 field of assisted reproduction;

6 (e) encouragement of the establishment and maintenance of a
7 national database in respect of infertility;

8 (f) guidelines for counselling and providing patients with all
9 necessary information and advice on various aspects of assisted
10 reproductive technology procedures;

11 (g) ways and means of disseminating information related to
12 infertility and assisted reproductive technologies to various sections of the
13 society;

14 (h) regulations in respect of research on human embryos;

15 (i) proformae for 'obtaining information from donors of gametes
16 and surrogate mothers, consent forms for various procedures, and contracts
17 and/or agreements between the various parties involved;

18 (j) policies from time to time on assisted reproduction.

19 6.-(1) Every State Government shall, within 180 days of the issue
20 of the notification under sub-section (1) of section 3, by notification in the
21 Official Gazette, establish a State Board for Assisted Reproductive
22 Technology to exercise the jurisdiction and powers and discharge the
23 functions and duties conferred or imposed on the State Boards by or under
24 this Act.

Establishment of
State Boards

25 (2) The State Boards shall consist of such number of members, not
26 exceeding twelve, as may be prescribed by the State Government and,
27 unless the rules otherwise provide, the State Boards shall consist of the
28 following members, namely:

29 (a) The Secretary of the Department of Health and Family Welfare,
30 who shall be Chairperson, ex officio;

1 (b) The nominee of an professional society concerned primarily with
2 assisted reproduction who shall be the Vice Chairperson, ex officio;

3 (c) An officer not below the rank of a Joint Secretary, who shall be the
4 Member-Secretary of the Board;

5 (d) Up to nine other members - of whom at least four shall be women -
6 who shall be experts in the fields of assisted reproduction, gynaecology,
7 embryology, andrology, bioethics, mammalian reproduction, medical
8 genetics, social science, law, or human rights, to be nominated by the State
9 Government.

10 (3) The Chairman of the State Board shall nominate a Vice Chairman
11 from among its members.

Meetings of
State Boards

12 7.-(1) The State Board shall meet as and when necessary, but not less
13 than three times a year and at such time and place as the Chairperson of the
14 State Board may think fit.

15 (2) The Chairperson of the State Board shall preside over the
16 meetings of the State Board.

17 (3) If for any reason the Chairperson of the State Board is unable to
18 attend any meeting of the State Board, the Vice Chairperson of the State Board
19 shall preside over the meeting.

Powers and
functions of State
Boards

20 8.-(1) Subject to the provisions of this Act and the rules and
21 regulations adopted thereunder, the State Board shall have the responsibility
22 for laying down the policies and plans for assisted reproduction in the State.

23 (2) Without prejudice to the generality of the provisions contained in
24 subsection (1) of this section, the State Board, taking into account the
25 recommendations, policies and regulations of the National Board, may:

26 (a) advise the State Government to constitute a Registration Authority
27 or Authorities as required, at least of six experts in assisted reproduction
28 technology or a related field, for the use of assisted reproductive technology in
29 the State;

30 (b) monitor the functioning of the Registration Authority subject, in

1 particular, to the guidelines laid down by the National Advisory Board;

2 (c) coordinate the enforcement and implementation of the policies
3 and guidelines for assisted reproduction;

4 (d) constitute advisory committees consisting of experts in the
5 field of assisted reproduction and related fields at the State or district level,
6 to make recommendations on different aspects of assisted reproduction;

7 (e) perform such other functions prescribed under this Act.

8 (3) Notwithstanding anything contained in section 12 of this Act,
9 the State Board may, suo motu, whether on the basis of a complaint or
10 otherwise, examine and review any decision of the Registration Authority.

11 (4) In the exercise of its functions under this Act, the State Board
12 shall give such directions or pass such orders as are necessary, with reasons
13 to be recorded in writing.

14 9.-(1) Before appointing any person as the Chairperson or other
15 member, the appropriate Government shall satisfy itself that the person's
16 integrity is such that his / her professional interest shall not affect
17 prejudicially his functions as such member.

Term of office,
conditions of
service, etc., of
Chairperson and
other members of
State Boards

18 (2) The Chairperson and every other Member shall hold office for
19 such period, not exceeding five years, as may be specified by the appropriate
20 government in the order of his appointment, but shall be eligible for re-
21 appointment.

22 (3) Notwithstanding anything contained in sub-section (1) of this
23 section, a member may by writing under his / her hand and addressed to the
24 appropriate Government resign his / her office at any time;

25 (4) A vacancy caused by the resignation or removal of the
26 Chairperson or any other member shall be filled by fresh appointment.

27 (5) In the event of the occurrence of a vacancy in the office of the
28 Chairperson by reason of his / her death, resignation or otherwise, such one
29 of the members as the appropriate Government may, by notification,
30 authorise in this behalf, shall act as the Chairperson till the date on which a

1 new Chairperson, appointed in accordance with the provisions of this Act to fill
2 such vacancy, takes charge of the office.

3 (6) When the Chairperson is unable to discharge his / her functions
4 owing to absence, illness or any other cause, the Vice Chairperson shall
5 discharge the function of the Chairpersons, till the date on which the
6 Chairperson resumes his duties.

7 (7) The salaries and allowances payable to and the other terms and
8 conditions of service of the Chairperson and other members shall be such as
9 may be prescribed; provided that neither the salary and allowances nor the
10 other terms and conditions of service of the Chairperson or any other member
11 shall be varied to his disadvantage after his appointment.

12 (8) The Chairperson and every other member shall, before entering
13 upon his / her office make a declaration of fidelity and secrecy in the form set
14 out in the Schedule.

15 (9) The Chairperson ceasing to hold office as such shall not hold any
16 appointment or be connected with the management or administration in any
17 company, hospital, clinic, society, trust or other undertaking in relation to
18 which any matter has been the subject matter of consideration before the State
19 Board, for a period of three years from the date on which he ceases to hold such
20 office.

Procedure of
State Boards

21 **10.-(1)** Subject to the provisions of this Act, the State Board shall have
22 powers to:

23 (a) regulate the procedure and conduct of the business;

24 (b) delegate its powers or functions to such persons or authorities as
25 prescribed in the rules or regulations made under this Act.

26 (2) The State Boards shall, for the purposes of any inquiry or for any
27 other purpose under this Act, have the powers to:

28 (a) summon and enforce the attendance of any witness and examine
29 him / her on oath;

30 (b) order the discovery and production of document or other material

1 objects producible as evidence;

2 (c) receive evidence on affidavit;

3 (d) requisition any public record from any court or office;

4 (e) issue any order for the examination of witnesses;

5 (f) any other matter which may be prescribed.

6 11.-(1) The State Government shall constitute the Registration
7 Authority as per the advise of the State Board, within a period of three
8 months of the advise.

Constitution and
functions of the
Registration
Authority

9 (2) The Registration Authority shall have a full-time Chairman of
10 the level of a Secretary to the State Government, who shall be a recognised
11 expert in assisted reproductive technology or a related field.

12 (3) The other members of the Registration Authority shall be part-
13 time members, and shall be adequately compensated for their services.

14 (4) Before appointing any member of the Registration Authority,
15 the Government shall satisfy itself that his / her integrity is such that his / her
16 professional interest shall not affect prejudicially his / her functions as a
17 member.

18 (5) The Registration Authority shall be provided by the State
19 Government with adequate supporting staff and secretarial assistance, and
20 suitable accommodation.

21 (6) The Registration Authority shall issue an appropriate letter
22 granting or rejecting registration to an assisted reproductive technology
23 clinic.

24 12. The National Board and every State Board shall be deemed to
25 be a civil court for the purposes of section 195 and Chapter XXVI of the
26 Code of Criminal Procedure, 1973, and every proceeding before the
27 National Board or every State Board shall be deemed to be a judicial
28 proceeding within the meaning of sections 193 and 228 and for the purposes
29 of section 196 of the Nigerian Penal Code, 1860.

Proceedings
before State
Boards to be
judicial proceedings

1 CHAPTER III - PROCEDURES FOR REGISTRATIONS AND COMPLAINTS

Registration and
accreditation of
clinics

2 13.-(1) All assisted reproductive technology clinics shall, within such
3 period and in such form and manner as may be prescribed, register themselves
4 with the Registration Authority.

5 (2) An application for registration by an assisted reproductive
6 technology clinic under sub-section (1) of this section shall contain the
7 particulars of the applicant including all details of techniques and procedures
8 of assisted reproductive technology practiced at such clinic.

9 (3) The State Board may, subject to such terms and conditions as may
10 be prescribed, register any assisted reproductive technology clinic on the basis
11 of the techniques and procedures of assisted reproductive technology practiced
12 at such clinic, namely:

13 (a) infertility treatment, including Intra-Uterine Insemination (IUI),
14 Artificial Insemination with Husband's semen (AIH), and Artificial
15 Insemination using Donor Semen (AID), involving the use of donated or
16 collected gametes;

17 (b) infertility treatment involving the use and creation of embryos
18 outside the human body;

19 (c) processing or storage of gametes and embryos;

20 (d) research on embryos.

21 (4) Notwithstanding anything contained in this Act or any of the Rules
22 made thereunder, no assisted reproductive technology clinic performing any of
23 the functions under sub-section (3) of this section, or any other advanced
24 diagnostic, therapeutic or research functions, shall practice any aspect of such
25 diagnosis, therapy or research without a certificate of accreditation issued by
26 the State Board.

27 (5) The practice of any aspect of assisted reproductive technology in
28 contravention of the provisions of this section shall constitute an offence under
29 this Act.

30 (6) Assisted reproductive technology clinics registered under this Act

1 shall be deemed to have satisfied the provisions of the PC & PNDT Act,
2 1994 (amended in 2002), and shall not be required to seek a separate
3 registration under the said Act.

4 14.-(1) Assisted reproductive technology clinics, semen banks and
5 research organizations using human embryos, operative on the date of
6 notification of this Act, shall obtain a temporary registration within six
7 months of the notification of the State Registration Authority by the State
8 Board, and regular registration within 18 months of the above notification. If
9 an assisted reproductive technology clinic that has applied for temporary
10 registration under this clause to the State Registration Authority does not
11 receive the registration or hear from the above Authority within 60 days of
12 the receipt of the application by the Authority, the clinic would be deemed to
13 have received the temporary registration.

Who may apply
for registration

14 (2) No assisted reproductive technology clinic, semen bank or
15 research organisation using human embryos, other than the ones specified
16 above, shall practice any aspect of assisted reproductive technology, or carry
17 out any research on or using human embryos, or use any premises for such
18 purposes, without a registration under this Act.

19 (3) Any assisted reproductive technology clinic or semen bank or
20 research organisation using human embryos, by whatsoever name called,
21 may apply to the Registration Authority for registration to operate the clinic,
22 semen bank or research organisation in accordance with the procedure and
23 criteria laid down in this Act.

24 (4) Every application under sub-section (2) of this section shall be
25 in such form and shall be accompanied by such fee and such documents as
26 may be prescribed by the State Government.

27 15.-(1) The Registration Authority may, if it is satisfied that the
28 criteria specified in the Rules have been met, grant registration to the
29 applicant for a term of three years under such terms and conditions as it
30 thinks fit.

Grant of
registration

1 (2) The Registration Authority shall, within one month of a
2 registration being granted under this section, report such registration to the
3 State Board.

4 (3) The State Board shall maintain a record of all registrations applied
5 for and granted under this section.

6 (4) No registration shall be granted unless the Registration Authority,
7 or such authorised person or persons acting on its behalf, have inspected the
8 premises of the applicant.

Renewal,
suspension or
revocation of
registration

9 16.-(1) The Registration Authority may, on an application made to it
10 in such form and manner as may be prescribed, renew a registration granted
11 under the provisions of this Act with effect from the date of its expiry if it is
12 satisfied that the criteria prescribed in the Schedule continue to be met.

13 (2) The Registration Authority may at any time suspend the operation
14 of a registration and call upon the holder of the registration to produce such
15 documents or furnish such evidence as may be required if it has reasonable
16 grounds to believe that the terms and conditions of the registration have not
17 been met.

18 (3) When acting under sub-section (2) of this section, the Registration
19 Authority shall either revoke the registration or continue the registration, as the
20 case may be, after giving the holder of the registration adequate opportunity to
21 be heard.

22 (4) The Registration Authority shall inform the concerned State
23 Board of every assisted reproductive technology clinic in respect of which it
24 has granted, renewed, revoked or denied a registration under this Act within
25 one month of such an action being taken.

26 (5) The Registration Authority shall be deemed to have granted
27 renewal for three years to the applicant if the applicant does not receive a
28 definitive communication from the Registration Authority regarding the
29 renewal application within sixty days of the receipt of the application in the
30 office of the Registration Authority.

1 17. In the exercise of its powers under this Act, the Registration
2 Authority shall have the power to inspect, with or without prior notice, any
3 premises or call for any document or material in the discharge of its powers
4 and functions.

Registration
Authority to
inspect premises

5 18. The provisions of sections 12 to 16 shall apply also to semen
6 banks and research organisations using human embryos.

Applicability to
semen banks and
research organizations

7 19.-(1) Any person aggrieved by the decision of the Registration
8 Authority made under this Act may, within such period and in such manner
9 and form as may be prescribed, prefer an appeal to the State Board.

Appeal to the
State Board

10 (2) On receipt of an appeal under sub-section (1) of this section, the
11 State Board may, after giving an opportunity to the appellant to be heard, and
12 after making such further inquiry as it thinks fit, confirm, modify or set aside
13 the decision of the Registration Authority, within three months of the receipt
14 of the appeal.

15 CHAPTER IV - DUTIES OF AN ASSISTED REPRODUCTIVE

16 TECHNOLOGY CLINIC

17 20.-(1) Assisted reproductive technology clinics shall ensure that
18 patients, donors of gametes and surrogate mothers are eligible to avail of
19 assisted reproductive technology procedures under the criteria prescribed
20 by the rules under this Act and that they have been medically tested for such
21 diseases, sexually transmitted or otherwise, as may be prescribed and all
22 other communicable diseases which may endanger the health of the parents,
23 or anyone of them, surrogate or child.

General duties
of assisted
reproductive
technology clinics

24 (2) It shall be the responsibility of an assisted reproductive
25 technology clinic to obtain, from semen bank(s), all relevant information,
26 other than the name, personal identity and address, of possible gamete
27 donors, and assist the couple or individual desirous of the donation, to
28 choose the donor.

29 (3) When a semen bank receives a request from an assisted
30 reproductive technology clinic for a donor oocyte, a responsible member of

1 the staff of the semen bank will accompany the particular donor to the Assisted
2 Reproductive Technology clinic, and obtain a written agreement from the
3 authority designated for this purpose by the clinic, that the clinic shall, under no
4 circumstances (except when asked by a court of law), reveal the identity of the
5 donor to the recipient couple or individual or to anyone else; the clinic shall
6 also ensure that all its staff is made aware of the fact that any step leading to
7 disclosure of the identify (i.e., name and address) to the recipient couple or
8 individual or to anyone else, shall amount to an offence punishable under this
9 Act.

10 (4) Either of the parties seeking assisted reproductive technology
11 treatment or procedures shall be entitled to specific information in respect of
12 donor of gametes including, but not restricted to, height, weight, ethnicity, skin
13 colour, educational qualifications, medical history of the donor, provided that
14 the identity, name and address of the donor is not made known.

15 (5) Assisted reproductive technology clinics shall obtain donor
16 gametes from semen banks that have ensured that the donor has been medically
17 tested for such diseases, sexually transmitted or otherwise, as may be
18 prescribed and all other communicable diseases which may endanger the
19 health of the parents, or anyone of them, surrogate or child.

20 (6) Assisted reproductive technology clinics shall provide
21 professional counselling to patients or individuals about all the implications
22 and chances of success of assisted reproductive technology procedures in the
23 clinic and in Nigeria and internationally, and shall also inform patients and
24 individuals of the advantages, disadvantages and cost of the procedures, their
25 medical side effects, risks including the risk of multiple pregnancy, the
26 possibility of adoption, and any such other matter as may help the couple or
27 individual arrive at a decision that would be most likely to be the best for the
28 couple or individual.

29 (7) Assisted reproductive technology clinics shall make couples or
30 individuals, as the case may be, aware of the rights of a child born through the

1 use of assisted reproductive technology.

2 (8) Assisted reproductive technology clinics shall explain to
3 couples or individuals, as the case may be, the choice or choices of treatment
4 available to them and the reason or reasons of the clinic for recommending a
5 particular treatment, and shall clearly explain the advantages,
6 disadvantages, limitations and cost of any recommended or explained
7 treatment or procedure.

8 (9) Assisted reproductive technology clinics shall ensure that
9 information about clients, donors and surrogate mothers is kept confidential
10 and that information about assisted reproductive technology treatment shall
11 not be disclosed to anyone other than a Federal database to be maintained by
12 the In Council of Medical Research, except with the consent of the person or
13 persons to whom the information relates, or in a medical emergency at the
14 request of the person or persons or the closest available relative of such
15 person or persons to whom the information relates, or by an order of a court
16 of competent jurisdiction.

17 (10) No assisted reproductive technology clinic shall consider
18 conception by surrogacy for patients for whom it would normally be
19 possible to carry a baby to term.

20 Provided that where it is determined that unsafe or undesirable medical
21 implications of such conception may arise, the use of surrogacy may be
22 permitted.

23 (11) Assisted reproductive technology clinics shall provide to
24 couples or individuals, as the case may be, a pre-stamped self-addressed
25 envelope to inform the clinic of the results of the assisted reproductive
26 technology procedure performed for the couple or the individual.

27 (12) No assisted reproductive technology clinic shall obtain or use
28 sperm or oocyte donated by a relative or known friend of either of the parties
29 seeking assisted reproductive technology treatment or procedures.

30 (13) Every assisted reproductive technology clinic shall establish a

1 mechanism to look into complaints in such manner as may be prescribed.

2 (14) No assisted reproductive technology procedure shall be
3 performed on a woman below 21 years of age, and any contravention of this
4 stipulation shall amount to an offence punishable under this Act.

5 (15) All assisted reproductive technology clinics shall issue to the
6 infertile couple / individual a discharge certificate stating details of the assisted
7 reproductive technology procedure(s) performed on the couple / individual.

Duty of the
assisted
reproductive
technology
clinic to obtain
written consent

8 21.-(1) No assisted reproductive technology clinic shall perform any
9 treatment or procedure of assisted reproductive technology without the
10 consent in writing of all the parties seeking assisted reproductive technology to
11 all possible stages of such treatment or procedures including the freezing of
12 embryos.

13 (2) No assisted reproductive technology clinic shall freeze any human
14 embryos without specific instructions and consent in writing from all the
15 parties seeking assisted reproductive technology in respect of what should be
16 done with the gametes or embryos in case of death or incapacity of any of the
17 parties.

18 (3) No assisted reproductive technology clinic shall use any human
19 reproductive material to create an embryo or use an in vitro embryo for any
20 purpose without the specific consent in writing of all the parties to whom the
21 assisted reproductive technology relates.

22 (4) The consent of any of the parties obtained under this section may
23 be withdrawn at any time before the embryos or the gametes are transferred to
24 the concerned woman's uterus.

Duty of assisted
reproductive
technology clinic
to keep accurate
records

25 22.-(1) All assisted reproductive technology clinics shall maintain
26 detailed records, in such manner as may be prescribed, of all donor oocytes,
27 sperm or embryos used, the manner and technique of their use, the individual or
28 couple or surrogate mother, in respect of whom it was used, and the
29 deoxyribonucleic acid (DNA) fingerprint of the individual or couple and the

1 child born as a result of assisted reproductive technology treatment or
2 procedures.

3 (2) All assisted reproductive technology clinics will, as and when
4 such Federal facilities are established, put on line all information available
5 to them in regard to progress of the patient (such as biochemical and clinical
6 pregnancy) within seven days of the information being available,
7 withholding the identity of the patient.

8 (3) Records maintained under sub-section (1) of this section shall
9 be maintained for at least a period of ten years, upon the expiry of which the
10 assisted reproductive technology clinic shall transfer the records to a
11 Federal database of the Nigerian Council of Medical Research.

12 (4) In the event of the closure of any assisted reproductive
13 technology clinic or semen bank before the expiry of the period of ten years
14 under sub-section (2) of this section, the assisted reproductive technology
15 clinic or semen bank shall immediately transfer the records to a Federal
16 database of the Nigerian Council of Medical Research.

17 **23.-(1)** Assisted reproductive technology clinics shall harvest
18 oocytes in accordance with such regulations of the National Board or
19 concerned State Board or any rule as may be prescribed under this Act.

Duties of assisted
reproductive
technology clinics
using gametes and
embryos

20 (2) The number of oocytes or embryos that may be placed in a
21 woman in anyone cycle shall be according to the rules and regulations
22 provided under this Act.

23 (3) No woman should be treated with gametes or embryos derived
24 from the gametes of more than one man or woman during anyone treatment
25 cycle.

26 (4) The ART clinic shall never mix semen from two individuals
27 before use.

28 (5) Where a multiple pregnancy occurs as a result of assisted
29 reproductive technology, the concerned assisted reproductive technology
30 clinic shall inform the patient immediately of the multiple pregnancy and its

1 medical implications and shall, if so instructed by the patient, carry out foetal
2 reduction.

3 (6) The collection of gametes from a person whose death is imminent
4 shall only be permissible if such person's spouse intends to avail assisted
5 reproductive technology to have a child.

6 (7) No assisted reproductive technology clinic shall use ova that are
7 derived from a foetus, in any process of in vitro fertilisation.

8 (8) No assisted reproductive technology clinic shall utilise any
9 semen, whether from a semen bank or otherwise, for any aspect of assisted
10 reproductive technology unless such semen is medically analysed in such
11 manner as may be prescribed.

12 (9) Any contravention of stipulation under sub-section 3, 4, 7 and 8 of
13 this section shall amount to an offence under this Act.

Pre-implantation
Genetic Diagnosis

14 **24.-(1)** Pre-implantation Genetic Diagnosis shall be used only to
15 screen the embryo for known, pre-existing, heritable or genetic diseases or as
16 specified by the Registration Authority.

17 (2) Destruction or donation (with the approval of the patient) to an
18 approved research laboratory for research purposes, of an embryo after Pre-
19 implantation Genetic Diagnosis, shall be done only when the embryo suffers
20 from pre-existing, heritable, life-threatening or genetic diseases

21 (3) The State Board may lay down such other conditions as it deems
22 fit in the interests of Pre-implantation Genetic Diagnosis.

Sex selection

23 **25.-(1)** No assisted reproductive technology clinic shall offer to
24 provide a couple with a child of a pre-determined sex.

25 (2) It shall be a criminal offence and it is prohibited for anyone to do
26 any act, at any stage, to determine the sex of the child to be born through the
27 process of assisted reproductive technology.

28 (3) No person shall knowingly provide, prescribe or administer
29 anything that would ensure or increase the probability that an embryo shall be
30 of a particular sex, or that would identify the sex of an in vitro embryo, except

1 to diagnose, prevent or treat a sex-linked disorder or disease.

2 (4) No assisted reproductive technology clinic will carry out any
3 assisted reproductive technology procedure to separate, or yield fractions
4 enriched in sperm of X or Y variations.

5 (5) Any contravention of stipulation under sub-section 1, 2, 3 and 4
6 of this section shall amount to an offence under this Act.

7 CHAPTER V - SOURCING, STORAGE, HANDLING AND RECORD KEEPING

8 FOR GAMETES, EMBRYOS AND SURROGATES

9 26.-(1) The collection, screening, storage and handling of gametes
10 shall be done by a semen bank registered as an independent entity under the
11 provisions of this Act. Sourcing of
gametes

12 (2) A semen bank shall operate independently of any assisted
13 reproductive technology clinic.

14 (3) Semen banks shall obtain semen from males between twenty
15 one years of age and forty five years of age, both inclusive, and arrange to
16 obtain oocytes from females between twenty one years of age and thirty five
17 years of age, both inclusive, and examine the donors for such diseases,
18 sexually transmitted or otherwise, as may be prescribed, and all other
19 communicable diseases which may endanger the health of the parents, or
20 anyone of them, surrogate or child.

21 (4) All semen banks shall have standard, scientifically established
22 facilities and defined standard operating procedures for the cryo-
23 preservation of sperm and oocytes.

24 (5) All semen banks shall cryo-preserve sperm donations for a
25 quarantine period of at least six months before being used and, at the expiry
26 of such period, the semen bank shall not supply the sperm to any assisted
27 reproductive technology clinic unless the sperm donor is tested for such
28 diseases, sexually transmitted or otherwise, as may be prescribed.

29 (6) A semen bank may advertise for gamete donors and surrogates,
30 who may be compensated financially by the bank.

1 (7) A semen bank shall not supply the sperm of a single donor for use
2 more than seventy five times.

3 (8) No woman shall donate oocytes more than six times in her life,
4 with not less than a three-months interval between the oocyte pick-ups.

5 (9) If more than fourteen (14) oocytes are retrieved from the donor at
6 one occasion, they shall not be used for more than two recipients thus ensuring
7 that at least seven oocytes are available for each recipient.

8 (10) One sample of semen supplied by a semen bank shall be used by
9 the ART clinic only once on only one recipient.

10 (11) A semen bank shall obtain all necessary information in respect of
11 a sperm or oocyte donor or a surrogate, including the name, identity and
12 address of such donor or surrogate, in such manner as may be prescribed, and
13 shall undertake in writing to the donor to keep such information confidential.

14 (12) No semen bank shall divulge the name, identity or address of any
15 sperm donor to any person or assisted reproductive technology clinic except in
16 pursuance of an order or decree of a court of competent jurisdiction.

17 (13) Any person or semen bank who divulges the name, identity or
18 address of a sperm donor in contravention of subsections 11 and 12 of this
19 section shall be guilty of an offence under this Act.

20 (14) A semen bank may, for such appropriate fee as may be
21 prescribed, store any semen obtained from a donor for the exclusive use of the
22 wife or partner of the donor.

23 27.-(1) The highest possible standards should be followed in the
24 storage and handling of gametes and embryos in respect of their security, and
25 with regard to their recording and identification.

26 (2) No gamete shall be stored for a period of more than ten years.

27 (3) An embryo may, for such appropriate fee as may be prescribed, be
28 stored for a maximum period of five years and at the end of such period such
29 embryo shall be allowed to perish or donated to an approved research
30 organization for research purposes with the consent of the patients. Provided

1 that where the persons to whom such embryo relates fails to pay the fee, the
2 assisted reproductive technology clinic may, subject to such regulations as
3 may be prescribed, destroy the embryo or transfer the embryo to any
4 accredited research organisation under section 13 of this Act.

5 28.-(1) The semen bank shall keep a record of all the gametes
6 received, stored and supplied, and details of the use of the gametes of each
7 donor. Records to be
maintained by
semen bank

8 (2) The records shall be maintained for at least ten years, after
9 which the records shall be transferred to a Federal database of the Nigerian
10 Council of Medical Research.

11 (3) Where an assisted reproductive technology clinic closes before
12 the expiry of the ten year period, the records shall be immediately
13 transferred to the Federal database of the Nigerian Council of Medical
14 Research.

15 (4) If not otherwise ordered by a court of competent jurisdiction, all
16 semen banks shall ensure that all information about clients and donors is
17 kept confidential and that information about gamete donation shall not be
18 disclosed to anyone other than the Federal database of the Nigerian Council
19 of Medical Research.

20 29.-(1) The sale, transfer or use of gametes, zygotes and embryos,
21 or any part thereof or information related thereto, directly or indirectly to
22 any party outside Nigeria is prohibited and shall be deemed to be an offence
23 under this Act except in the case of transfer of own gametes and embryos for
24 personal use with the permission of the National Board. Restriction on
sale of gametes,
zygotes and
embryos

25 (2) The sale of gametes, except for use by an assisted reproductive
26 technology clinic for treating infertility, and the sale of zygotes and
27 embryos, or of any information related to gametes, zygotes or embryos,
28 within Nigeria, is prohibited and shall be deemed to be an offence under this
29 Act.

1 CHAPTER VI - REGULATION OF RESEARCH ON EMBRYOS

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Permission of
the Nigerian
Council of Medical
Research (ICMR)
for research

30.-(1) The sale of any gametes and embryos for research or their transfer to any country outside Nigeria, is absolutely prohibited and shall constitute a criminal offence under this Act.

(2) Research shall only be conducted on such gametes and embryos that have been donated for such purpose.

(3) No research shall be conducted using embryos except with the permission of the ICMR.

(4) Any person or organisation, by whatsoever name called, may apply to the ICMR for registration as a research institution permitted to conduct research on embryos.

(5) While granting permission on an application for registration made under sub-section 4 of this section, the ICMR may prescribe, and the applicant shall be bound by such terms and conditions as it thinks fit.

(6) The ICMR may, if it has reasonable grounds to believe that any of the terms and conditions prescribed under sub-section 5 of this section have not been met:

(a) call for the production of such documents or the furnishing of such evidence as may be required;

(b) inspect, or order any officer authorised in this behalf to inspect, any premises related to the grant of registration;

(c) suspend the registration of the research institution, after giving all concerned parties adequate opportunity to be heard.

(7) The ICMR may make such regulations as it thinks fit to provide for research on embryos.

(8) Any act or thing done or omitted to be done in contravention of the provisions of this Chapter shall be deemed to be an offence under this Act.

Regulation of
Research

31.-(1) In exercising its powers under this Chapter, the ICMR shall ensure that:

(a) no research is conducted on any human embryo unless such

1 research is necessary in public interest;

2 (b) no research is conducted on any human embryo created in vitro
3 unless such research is necessary in public interest to acquire further
4 scientific knowledge;

5 (c) no research is conducted on any human embryo, other than
6 embryos given for storage to a semen bank under sub-section

7 (3) of section 27, unless full and informed consent in writing is
8 obtained from the persons from whom such embryo was created;

9 (d) no advertisement is issued, and no purchase, sale or transfer is
10 made, of any human embryo created in vitro or any part thereof, except in
11 accordance with this Act;

12 (e) no human embryo created in vitro is maintained for a period
13 exceeding fourteen days or such other period as recommended by the
14 National Advisory Board;

15 (f) no work is done leading to human reproductive cloning;

16 (g) such other terms and conditions that may be prescribed by the
17 ICMR, are adhered to.

18 (2) Any assisted reproductive technology clinic or other research
19 institution or person conducting any research in contravention of the
20 provisions of this Act or any rules or regulations prescribed hereunder shall
21 be an offence under this Act.

22 CHAPTER VII - RIGHTS AND DUTIES OF PATIENTS, DONORS,

23 SURROGATES AND CHILDREN

24 32.-(1) Subject to the provisions of this Act and the rules and
25 regulations made thereunder, ART shall be available to all persons including
26 single persons, married couples and unmarried couples.

Rights and duties
of patients

27 (2) In case ART is used by a married or unmarried couple, there
28 must be informed consent from both the parties.

29 (3) The parents of a minor child have the right to access
30 information about the donor, other than the name, identity or address of the

1 donor, or the surrogate mother, when and to the extent necessary for the welfare
2 of the child.

3 (4) All information about the patients shall be kept confidential and
4 information about ART procedures done on them shall not be disclosed to
5 anyone other than the Federal depository of the ICMR, except with the consent
6 of the person or persons to whom the information relates, or by a court order.

Rights and duties
of donors

7 33.-(1) Subject to the other provisions of this Act, all information
8 about the donors shall be kept confidential and information about gamete
9 donation shall not be disclosed to anyone other than the Federal database of the
10 Nigerian Council of Medical Research, except with the consent of the person or
11 persons to whom the information relates, or by an order of a court of competent
12 jurisdiction.

13 (2) Subject to the other provisions of this Act, the donor shall have the
14 right to decide what information may be passed on and to whom, except in the
15 case of an order of a court of competent jurisdiction.

16 (3) A donor shall relinquish all parental rights over the child which
17 may be conceived from his or her gamete.

18 (4) No assisted reproductive technology procedure shall be
19 conducted on or in relation to any gamete of a donor under this Act unless such
20 donor has obtained the consent in writing of his or her spouse, if there, to such
21 procedure.

Rights and duties
in relation to
surrogacy

22 34.-(1) Both the couple or individual seeking surrogacy through the
23 use of assisted reproductive technology, and the surrogate mother, shall enter
24 into a surrogacy agreement which shall be legally enforceable.

25 (2) All expenses, including those related to insurance, of the surrogate
26 related to a pregnancy achieved in furtherance of assisted reproductive
27 technology shall, during the period of pregnancy and after delivery as per
28 medical advice, and till the child is ready to be delivered as per medical advice,
29 to the biological parent or parents, shall be borne by the couple or individual
30 seeking surrogacy.

1 (3) Notwithstanding anything contained in sub-section (2) of this
2 section and subject to the surrogacy agreement, the surrogate mother may
3 also receive monetary compensation from the couple or individual, as the
4 case may be, for agreeing to act as such surrogate.

5 (4) A surrogate mother shall relinquish all parental rights over the
6 child.

7 (5) No woman under twenty one years of age and over forty five
8 years of age shall be eligible to act as a surrogate mother under this Act.
9 Provided that no woman shall act as a surrogate for more than three
10 successful live births in her life.

11 (6) Any woman seeking or agreeing to act as a surrogate mother
12 shall be medically tested for such diseases, sexually transmitted or
13 otherwise, as may be prescribed, and all other communicable diseases
14 which may endanger the health of the child, and must declare in writing that
15 she has not undergone intravenous medical treatment or received a blood
16 transfusion.

17 (7) Individuals or couples may obtain the service of a surrogate
18 through a semen bank, or advertise to seek surrogacy provided that no such
19 advertisement shall contain any details relating to the caste, ethnic identity
20 or descent of any of the parties involved in such surrogacy. No assisted
21 reproductive technology clinic shall advertise to seek surrogacy for its
22 clients.

23 (8) A surrogate mother shall, in respect of all medical treatments or
24 procedures in relation to the concerned child, register at the hospital or such
25 medical facility in her own name, clearly declare herself to be a surrogate
26 mother, and provide the name or names and addresses of the person or
27 persons, as the case may be, for whom she is acting as a surrogate, along with
28 a copy of the certificate mentioned in clause 17 below.

29 (9) If the first embryo transfer has failed in a surrogate mother, she
30 may, if she wishes, decide to accept on mutually agreed financial terms, at

1 most two more successful embryo transfers for the same couple that had
2 engaged her services in the first instance. No surrogate mother shall undergo
3 embryo transfer more than three times for the same couple.

4 (10) The birth certificate issued in respect of a baby born through
5 surrogacy shall bear the name(s) of the genetic parents / parent of the baby.

6 (11) The person or persons who have availed of the services of a
7 surrogate mother shall be legally bound to accept the custody of the child /
8 children irrespective of any abnormality that the child / children may have, and
9 the refusal to do so shall constitute an offence under this Act.

10 (12) Subject to the provisions of this Act, all information about the
11 surrogate shall be kept confidential and information about the surrogacy shall
12 not be disclosed to anyone other than the Federal database of the Nigerian
13 Council of Medical Research, except by an order of a court of competent
14 jurisdiction.

15 (13) A surrogate mother shall not act as an oocyte donor for the couple
16 or individual, as the case may be, seeking surrogacy.

17 (14) No assisted reproductive technology clinic shall provide
18 information on or about surrogate mothers or potential surrogate mothers to
19 any person.

20 (15) Any assisted reproductive technology clinic acting in
21 contravention of sub-section 14 of this section shall be deemed to have
22 committed an offence under this Act.

23 (16) In the event that the woman intending to be a surrogate is
24 married, the consent of her spouse shall be required before she may act as such
25 surrogate.

26 (17) A surrogate mother shall be given a certificate by the person or
27 persons who have availed of her services, stating unambiguously that she has
28 acted as a surrogate for them.

29 (18) A relative, a known person, as well as a person unknown to the
30 couple may act as a surrogate mother for the couple. In the case of a relative

1 acting as a surrogate, the relative should belong to the same generation as the
2 women desiring the surrogate.

3 (19) A foreigner or foreign couple not resident in Nigeria, or a non-
4 resident Nigerian individual or couple, seeking surrogacy in Nigeria shall
5 appoint a local guardian who will be legally responsible for taking care of
6 the surrogate during and after the pregnancy as per clause 34.2, till the child/
7 children are delivered to the foreigner or foreign couple or the local
8 guardian. Further, the party seeking the surrogacy must ensure and establish
9 to the ART clinic through proper documentation that the party would be able
10 to take the child / children born through surrogacy, including where the
11 embryo was a consequence of donation of an oocyte or sperm, outside of
12 Nigeria to the country of the party's origin or residence as the case may be.

13 (20) A couple or an individual shall not have the service of more
14 than one surrogate at any given time.

15 (21) A couple shall not have simultaneous transfer of embryos in
16 the woman and in a surrogate.

17 35.-(1) A child born to a married couple through the use of assisted
18 reproductive technology shall be presumed to be the legitimate child of the
19 couple, having been born in wedlock and with the consent of both spouses,
20 and shall have identical legal rights as a legitimate child born through sexual
21 intercourse.

Determination
of status of the
child

22 (2) A child born to an unmarried couple through the use of assisted
23 reproductive technology, with the consent of both the parties, shall be the
24 legitimate child of both parties.

25 (3) In the case of a single woman the child will be the legitimate
26 child of the woman, and in the case of a single man the child will be the
27 legitimate child of the man.

28 (4) In case a married or unmarried couple separates or gets
29 divorced, as the case may be, after both parties consented to the assisted
30 reproductive technology treatment but before the child is born, the child

1 shall be the legitimate child of the couple.

2 (5) A child born to a woman artificially inseminated with the stored
3 sperm of her dead husband shall be considered as the legitimate child of the
4 couple.

5 (6) If a donated ovum contains ooplasm from another donor ovum,
6 both the donors shall be medically tested for such diseases, sexually
7 transmitted or otherwise, as may be prescribed, and all other communicable
8 diseases which may endanger the health of the child, and the donor of both the
9 ooplasm and the ovum shall relinquish all parental rights in relation to such
10 child.

11 (7) The birth certificate of a child born through the use of assisted
12 reproductive technology shall contain the name or names of the parent or
13 parents, as the case may be, who sought such use.

Right of the
child to
information
about donors or
surrogates

14 36.-(1) A child may, upon reaching the age of 18, apply for any
15 information, excluding personal identification, relating to his I her genetic
16 parent or parents or surrogate mother.

17 (2) The legal guardian of a minor child may apply for any
18 information, excluding personal identification, about his I her genetic parent or
19 parents or surrogate mother when required, and to the extent necessary, for the
20 welfare of the child.

21 (3) Personal identification of the genetic parent or parents or
22 surrogate mother may be released only in cases of life threatening medical
23 conditions which require physical testing or samples of the genetic parent or
24 parents or surrogate mother.

25 Provided that such personal identification will not be released without the prior
26 informed consent of the genetic parent or parents or surrogate mother.

Prohibition of
advertisement
relating to
pre-natal
determination
of sex and
punishment for
contravention

27 CHAPTER VIII - OFFENCES AND PENALTIES

28 37.-(1) No assisted reproductive technology clinic shall issue or cause
29 to be issued any advertisement in any manner regarding facilities of prenatal
30 determination of sex.

1 (2) No assisted reproductive technology clinic, or agent thereof,
2 shall publish or distribute or cause to be published or distributed any
3 advertisement in any manner regarding facilities of pre-natal determination
4 of sex.

5 (3) Any person who contravenes the provisions of this section shall
6 be punishable with imprisonment for a term which may extend to five years
7 and with fine which may be specified.

8 Explanation - For the purposes of this section, "advertisement" includes any
9 notice, circular, label wrapper or other document and also includes any
10 visible representation made by means of any light, sound, smoke or gas.

11 38.-(1) Any medical geneticist, gynaecologist, registered medical
12 practitioner or any person who owns or operates any assisted reproductive
13 technology clinic, or is employed in such a facility and renders his
14 professional or technical services to such facility, whether on an honorary
15 basis or otherwise, and who contravenes any of the provisions of this Act or
16 rules made thereunder, shall be punishable with imprisonment for a term
17 which may extend to three years and with fine which may be specified, and
18 on any subsequent conviction, with imprisonment which may extend to five
19 years and with fine which may be specified.*

Offences and
penalties

20 (2) The name of the registered medical practitioner who has been
21 convicted by the court under sub-section 1 of this section shall be reported
22 by the State Board to the respective State Medical Council for taking
23 necessary action including the removal of his name from the register or the
24 Council for a period of two years for the first offence and permanently for
25 any subsequent offence.

26 (3) Any person who seeks the aid of assisted reproductive
27 technology or of a medical geneticist, gynaecologist or registered medical
28 practitioner for conducting pre-natal diagnostic techniques on any pregnant
29 woman shall be punishable with imprisonment for a term which may extend
30 to three years and with fine which may be specified, and on any subsequent

1 conviction with imprisonment which may extend to five years and with fine
2 which may be specified.

3 (4) The transfer of a human embryo into a male person or into an
4 animal that is not of the human species shall be an offence under this Act and
5 shall be punishable with imprisonment for a term which may extend to three
6 years and with fine which may be specified.

7 (5) The sale of any embryo for research is absolutely prohibited and
8 shall be an offence under this Act punishable by imprisonment for a term which
9 may extend to three years and with fine which may be specified.

Presumption in
the case of conduct
of pre-natal
diagnostic
techniques

10 39. Notwithstanding anything in the Nigerian Evidence Act, 1872,
11 the court shall presume, unless the contrary is proved, that the pregnant woman
12 has been compelled by her husband or the relative to undergo pre-natal
13 diagnostic technique.

Penalty for
contravention of
the provisions of
the Act or rules
for which no
specific
punishment is
provided

14 40. Whoever contravenes any of the provisions of this Act or any
15 rules made thereunder, for which no penalty has been elsewhere provided in
16 this Act, shall be punishable with imprisonment for a term which may extend to
17 three years, or with fine which may be specified, or with both, and in the case of
18 continuing contravention, with an additional fine which may be specified.

Offences by
companies

19 41.-(1) Where any offence, punishable under this Act has been
20 committed by a company, every person who at the time the offence was
21 committed was in charge of, and was responsible to, the company for the
22 conduct of the business of the company, as well as the company, shall be
23 deemed to be guilty of the offence and shall be liable to be proceeded against
24 and punished accordingly:

25 Provided that nothing contained in this sub-section shall render any such
26 person liable to any punishment, if he proves that the offence was committed
27 without his knowledge or that he had exercised all due diligence to prevent the
28 commission of such offence.

29 (2) Notwithstanding anything contained in sub-section (1) of this
30 section, where any offence punishable under this Act has been committed by a

1 company and it is proved that the offence has been committed with the
 2 consent or connivance of, or is attributable to any neglect on the part of, any
 3 director, manager, secretary or other officer of the company, such director,
 4 manager, secretary or other officer shall also be deemed to be guilty of that
 5 offence and shall be liable to be proceeded against and punished
 6 accordingly.

7 Explanation: For the purposes of this section:

8 (a) "company" means anybody corporate and includes a firm or
 9 other association of individuals, and

10 * (b) "director", in relation to a firm, means a partner in the firm.

11 42. Every offence under this Act shall be cognizable, non-bailable
 12 and noncompoundable.

Offence to be
cognizable, non-
bailable and non-
compoundable

13 CHAPTER IX - MISCELLANEOUS

14 43.-(1) All records, charts, forms, reports, consent letters and all
 15 other documents required to be maintained under this Act and the rules shall
 16 be preserved for a period of ten years or for such period as may be prescribed
 17 Provided that, if any criminal or other proceedings are instituted against any
 18 facility using assisted reproductive technology, the records and all other
 19 documents of such facility shall be preserved till the final disposal of such
 20 proceedings.

Maintenance of
records

21 (2) All such records shall, at all reasonable times, be made
 22 available for inspection to the concerned State Board or to any other person
 23 authorised by the concerned State Board in this behalf.

24 44.-(1) If the State Board has reason to believe that an offence
 25 under this Act has been or is being committed at any facility using assisted
 26 reproductive technology, such Board or any officer authorised thereof in this
 27 behalf may, subject to such rules as may be prescribed, enter and search at all
 28 reasonable times with such assistance, if any, as such authority or officer
 29 considers necessary, such facility, and examine any record, register,
 30 document, book, pamphlet, advertisement or any other material object

Power to search
and records etc.

1 found therein and seize the same if the State Board or officer has reason to
2 believe that it may furnish evidence of the commission of an offence
3 punishable under this Act.

4 (2) The provisions of the Criminal Code Act, relating to searches and
5 seizures shall, so far as may be, apply to every search or seizure made under this
6 Act.

Power to remove
difficulties

7 45.-(1) If any difficulty arises in giving effect to the provisions of this
8 Act, the Federal Government may, by order published in the Official Gazette,
9 make such provisions not inconsistent with the provisions of this Act as may
10 appear to be necessary for removing the difficulty:
11 Provided that no order shall be made under this section after the expiry of three
12 years from the commencement of this Act.

13 (2) Every order made under this section shall be laid, as soon as may
14 be after it is made, before each House of Parliament.

Protection of
action taken in
good faith

15 46. No suit, prosecution or other legal proceeding shall lie against the
16 Federal or the State Government or the National Board or State Boards or
17 Registration Authority or any officer authorised by any of them, for anything
18 which is in good faith done or intended to be done in pursuance of the
19 provisions of this Act.

Power to make
regulations

20 47. The National Advisory Board may, with the previous sanction of
21 the Federal Government, by notification in the Official Gazette, make
22 regulations not inconsistent with the provisions of this Act and the rules made
23 thereunder, to provide for:

24 (a) the time and place of the meetings of the Board and the procedure
25 to be followed for the transaction of business at such meetings, and the number
26 of members which shall form the quorum;

27 (b) the conditions for the sale, transfer or hire of embryos and gametes
28 to research institutions;

29 (c) regulation of Pre-implantation Genetic Diagnosis;

30 (d) research on embryos;

1 (e) the efficient conduct of the affairs of the Board;

2 (f) any other purpose that may be prescribed.

3 **48.**-(1) The Federal Government may make rules for carrying out the provisions of this Act. Power of the
Federal Government
to make rules

4
5 (2) In particular, and without prejudice to the generality of the
6 foregoing power, such rules may provide for-

7 (a) categories of assisted reproductive technology clinics;

8 (b) the minimum requirements regarding staff in assisted
9 reproductive technology clinics;

10 (c) the minimum physical infrastructure requirements for an
11 assisted reproductive technology clinic;

12 (d) the various assisted reproductive technology procedures to be
13 adopted by an assisted reproductive technology clinic;

14 (e) the criteria for selecting patients for an assisted reproductive
15 technology procedure;

16 (f) the criteria for selecting an assisted reproductive technology
17 procedure for a patient;

18 (g) information and advise to, and counselling of patient;

19 (h) the eligibility of couples and individuals to use assisted
20 reproductive technology;

21 (i) the eligibility of donors;

22 (j) the eligibility of surrogate mothers;

23 (k) the number of embryos that can be implanted in a woman;

24 (l) the number of times that a patient can be given a procedure;

25 (m) the maintenance of records;

26 (n) procedure to search and seize;

27 (o) the criteria to be fulfilled for a license;

28 (p) the effective implementation of the Act.

29 (3) Every rule made by the Federal Government under sub-section
30 (1) of this section shall be laid, as soon as may be after it is made, before each

1 House of Parliament, while it is in session, for a total period of thirty days
2 which may be comprised in one session or in two or more successive sessions,
3 and if, before the expiry of the session immediately following the session or the
4 successive sessions aforesaid, both Houses agree in making any modification
5 in the rule or regulation or both Houses agree that the rule or regulation should
6 not be made, the rule or regulation shall thereafter have effect only in such
7 modified form or be of no effect, as the case may be; so, however, that any such
8 modification or annulment shall be without prejudice to the validity of
9 anything previously done under that rule or regulation.

Power of State
Government to
make rules

10 49. Subject to the provisions of this Act and the rules and regulations
11 made thereunder, the State Government may make rules to carry out the
12 purposes of this Act.

Act to have
effect in addition
to other Acts

13 50. The provisions of this Act shall be in addition to, and not in
14 derogation of, the provisions of any other law, for the time being in force.

EXPLANATORY MEMORANDUM

This Bill seeks to provide for a National framework for the regulation and supervision of reproductive technology.