

Draft

**THE
ASSISTED REPRODUCTIVE
TECHNOLOGIES (REGULATION)
BILL - 2010**



**MINISTRY OF HEALTH & FAMILY WELFARE
GOVT. OF INDIA, NEW DELHI**



**INDIAN COUNCIL OF MEDICAL RESEARCH
NEW DELHI**

**THE
ASSISTED REPRODUCTIVE TECHNOLOGY
(REGULATION) BILL - 2010**

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PREAMBLE

It is estimated that 15 percent of couples around the world are infertile. This implies that infertility is one of the most highly prevalent medical problems. The magnitude of the infertility problem also has enormous social implications. Besides the fact that every couple has the right to have a child, in India infertility widely carries with it a social stigma. In the Indian social context specially, children are also a kind of old-age insurance.

With the enormous advances in medicine and medical technologies, today 85 percent of the cases of infertility can be taken care of through medicines, surgery and/or the new medical technologies such as *in vitro* fertilization (IVF) or intracytoplasmic sperm injection (ICSI). It may be recalled that the birth of the first child, Louise Brown in 1978, through the technique of in vitro fertilization by Robert G Edwards and Patrick Steptoe, was a path-breaking step in control of infertility; it is, in retrospect, considered as one of the most important medical advances of the last century.

Most of the new technologies aimed at taking care of infertility, involve handling of the gamete – spermatozoa or the oocyte – outside the body; they also often involve the donation of spermatozoa or oocyte, or the use of a surrogate mother who would be carrying a child with whom she has no biological relationship. These technologies not only require expertise but also open up many avenues for unethical practices which can affect adversely the recipient of the treatment, medically, socially and legally.

The last nearly 20 years have seen an exponential growth of infertility clinics that use techniques requiring handling of spermatozoa or the oocyte outside the body, or the use of a surrogate mother. As of today, anyone can open infertility or assisted reproductive technology (ART) clinic; no permission is required to do so. There has been, consequently a mushrooming of such clinics around the country.

In view of the above, in public interest, it has become important to regulate the functioning of such clinics to ensure that the services provided are ethical and that the medical, social and legal rights of all those concerned are protected.

The bill details procedures for accreditation and supervision of infertility clinics (and related organizations such as semen banks) handling spermatozoa or oocytes outside of the body, or dealing with gamete donors and surrogacy, ensuring that the legitimate rights of all concerned are protected, with maximum benefit to the infertile couples/individuals within a recognized framework of ethics and good medical practice.

STATEMENT OF OBJECTS AND REASONS

An act to provide for a national framework for the accreditations, regulation and supervision of assisted reproductive technology clinics, for prevention of misuse of assisted reproductive technology, for safe and ethical practice of assisted reproductive technology services and for matters connected therewith or incidental thereto.

BE IT ENACTED by the Parliament in the 60th year of the Republic of India as follows:

CHAPTER - I

PRELIMINARY

1. Short title, extent and commencement –

- (1) This Act may be called the Assisted Reproductive Technology (Regulation) Act, 2010
- (2) It applies, in the first instance, to the whole States of and and the Union Territories; and it shall apply to such other States which adopt this Act by resolution passed in that behalf under Clause (1) of Article 252 of the Constitution.
- (3) It shall come into force at once in the States of and and the Union Territories, on such dates as the Central Government may, by notification appoint, and in any other States which adopt this Act under Clause (1) of Article 252 of the Constitution, on the date of such adoption; and any reference in this Act to the commencement of this Act shall, in relation to any State or Union Territory, mean the date on which this Act comes into force in such a State or Union Territory.

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

- a. “ART bank”, means an organisation that is set up to supply sperm / semen, oocytes / oocyte donors and surrogate mothers to assisted reproductive technology clinics or their patients;
- b. “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;
- c. “assisted reproductive technology” (ART), 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 reproductive tract;

- d. "assisted reproductive technology clinic", means any premises used for procedures related to assisted reproductive technology;
- e. "biological parent(s)", means genetic parent(s);
- f. "child", means any individual born through the use of assisted reproductive technology;
- g. "Commissioning parents/couples/individuals", means parents, couples or individuals, respectively, who approach an ART clinics or ART bank for providing a service that the ART Clinic or the ART bank is authorized to provide.
- h. "couple", means two persons living together and having a sexual relationship that is legal in India;
- i. "cryo-preservation", means the freezing and storing of gametes, zygotes and embryos;
- j. "Department of Health Research", means Department of Health Research, Ministry of Health and Family Welfare, Government of India;
- k. "donor", means the donor of a gamete or gametes but does not include the husband who provides the sperm or the wife who provides the oocyte to be used in the process of assisted reproduction for their own use;
- l. "egg", means the female gamete (that is, oocyte)
- m. "embryo", means the fertilized ovum that has begun cellular division and continued development up to eight weeks;
- n. "fertilization", means the penetration of the ovum by the spermatozoon and fusion of genetic materials resulting in the development of a zygote;
- o. "foetal reduction", means reduction in the number of foetuses in the case of multiple pregnancies;
- p. "foetus", means the product of conception, starting from completion of embryonic development until birth or abortion;
- q. "gamete", means sperm and oocyte (that is egg);
- r. "gamete donor", means a person who provides sperm or oocyte with the objective of enabling an infertile couple or individual to have a child;

- s. "Indian Council of Medical Research", means the Indian Council of Medical Research (ICMR) as registered under the Societies Registration Act, 1860;
- t. "implantation", means the attachment and subsequent penetration by the zona-free blastocyst, which starts five to seven days following fertilization;
- u. "infertility", means the inability to conceive after at least one year of unprotected coitus; or an anatomical / physiological condition that would prevent an individual from having a child;
- v. "married couple", means two persons whose marriage is legal in the country / countries of which they are citizens;
- w. "oocyte" and "ovum", mean, respectively, the female gamete (that is, egg) present in the ovary, and an ovulated oocyte in which the first polar body has been released;
- x. "patient(s)", means an individual / couple who comes to an infertility clinic and is under treatment for infertility;
- y. "Pre-implantation Genetic Diagnosis", includes the technique in which an embryo formed through in-vitro fertilisation is tested for specific disorders prior to the transfer;
- z. "sperm", means the male gametes produced in the testicles and contained in semen;
- aa. "surrogacy", means an arrangement in which a woman agrees to a pregnancy, achieved through assisted reproductive technology, in which neither of the gametes belong to her or her husband, with the intention to carry it and hand over the child to the person or persons for whom she is acting as a surrogate;
- bb. "surrogate mother", means a woman who is a citizen of India and is resident in India, who agrees to have an embryo generated from the sperm of a man who is not her husband and the oocyte of another woman, implanted in her to carry the pregnancy to viability and deliver the child to the couple / individual that had asked for surrogacy;
- cc. "surrogacy agreement", means a contract between the person(s) availing of assisted reproductive technology and the surrogate mother;
- dd. "unmarried couple", means two persons, both of marriageable age, living together with mutual consent but without getting married, in a relationship that is legal in the country / countries of which they are citizens;
- ee. "zygote", means the fertilized oocyte prior to the first cell division.

CHAPTER - II

CONSTITUTION OF AUTHORITIES TO REGULATE ASSISTED REPRODUCTIVE TECHNOLOGY

3. Establishment of National Advisory Board –

- (1) With effect from such date as the Central Government may, by notification, appoint, there shall be established a Board to be known as the National Advisory Board for Assisted Reproductive Technology, hereafter referred to as the National Board, to exercise the jurisdiction and powers and discharge the functions and duties conferred or imposed on the Board by or under this Act.
- (2) The National Board shall consist of such number of members, not exceeding twenty one, as may be prescribed by the Central Government and, unless the rules otherwise provide, the National Board shall consist of the following –
 - (a) Secretary, Department of Health Research, Government of India, who shall be the Chairman of the Board;
 - (b) A senior scientist having knowledge of assisted reproductive technology, from the Department of Health Research or the Indian Council of Medical Research, who shall be the Member-Secretary of the Board;
 - (c) A representative, not below the rank of Joint Secretary, from the Ministry of Health and Family Welfare;
 - (d) The nominee of an Indian professional society concerned primarily with assisted reproduction;
 - (e) Up to sixteen other experts – of whom one each shall be a nominee of the Ministry of Health and Family Welfare and Indian Council of Medical Research, and at least six of whom shall be women – in the fields of assisted reproduction, gynaecology, embryology, andrology, bioethics, mammalian reproduction, medical genetics, social science, law, or human rights, to be nominated by the Central Government.
- (3) The Chairman of National Board shall nominate a Vice Chairman from among its members.

4. Meetings of National Advisory Board –

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

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

5. Functions of National Advisory Board –

- (1) The National Board may recommend modification from time to time in the attached rules and schedules where relevant in regard to the following, and perform any other functions and tasks assigned to it by the Central Government:
 - (a) minimum requirements related to staff and physical infrastructure for the various categories of assisted reproductive technology clinics;
 - (b) regulations in respect of permissible assisted reproductive technology procedures;
 - (c) regulations in respect of selection of patients for assisted reproductive technology procedures;
 - (d) encouragement and promotion of training and research in the field of assisted reproduction;
 - (e) encouragement of the establishment and maintenance of a national database in respect of infertility;
 - (f) guidelines for counselling and providing patients with all necessary information and advice on various aspects of assisted reproductive technology procedures;
 - (g) ways and means of disseminating information related to infertility and assisted reproductive technologies to various sections of the society;
 - (h) regulations in respect of research on human embryos;
 - (i) proforma for obtaining information from donors of gametes and surrogate mothers, consent forms for various procedures, and contracts and / or agreements between the various parties involved, in all of the languages listed in the Eighth Schedule of the Constitution;
 - (j) policies from time to time on assisted reproduction;

6. Establishment of State Boards –

- (1) Every State Government shall, within 180 days of the issue of the notification under sub-section (1) of section 3, by notification in the Official Gazette, establish a State Board for Assisted Reproductive Technology to exercise the jurisdiction and powers and discharge the functions and duties conferred or imposed on the State Boards by or under this Act.
- (2) The State Boards shall consist of such number of members, not exceeding twelve, as may be prescribed by the State Government and, unless the rules otherwise provide, the State Boards shall consist of the following members, namely –
 - (a) The Secretary of the Department of Health and Family Welfare, who shall be Chairperson, *ex officio*;
 - (b) The nominee of an Indian professional society concerned primarily with assisted reproduction who shall be the Vice Chairperson, *ex officio*;
 - (c) An officer not below the rank of a Joint Secretary, who shall be the Member-Secretary of the Board;
 - (d) Up to nine other members – of whom at least four shall be women – who shall be experts in the fields of assisted reproduction, gynaecology, embryology, andrology, bioethics, mammalian reproduction, medical genetics, social science, law, or human rights, to be nominated by the State Government.
- (3) The Chairman of the State Board shall nominate a Vice Chairman from among its members.

7. Meetings of State Boards –

- (1) The State Board shall meet as and when necessary, but not less than three times a year, and at such time and place as the Chairperson of the State Board may think fit.
- (2) The Chairperson of the State Board shall preside over the meetings of the State Board.
- (3) If for any reason the Chairperson of the State Board is unable to attend any meeting of the State Board, the Vice Chairperson of the State Board shall preside over the meeting.

8. Powers and functions of State Boards –

- (1) Subject to the provisions of this Act and the rules and regulations adopted thereunder, the State Board shall have the responsibility for

laying down the policies and plans for assisted reproduction in the State.

- (2) Without prejudice to the generality of the provisions contained in subsection (1) of this section, the State Board, taking into account the recommendations, policies and regulations of the National Board, may –
 - (a) advise the State Government to constitute a Registration Authority or Authorities as required, at least of six experts in assisted reproduction technology or a related field, for the use of assisted reproductive technology in the State;
 - (b) monitor the functioning of the Registration Authority subject, in particular, to the guidelines laid down by the National Advisory Board;
 - (c) coordinate the enforcement and implementation of the policies and guidelines for assisted reproduction;
 - (d) constitute advisory committees consisting of experts in the field of assisted reproduction and related fields at the State or district level, to make recommendations on different aspects of assisted reproduction;
 - (e) perform such other functions prescribed under this Act;
- (3) Notwithstanding anything contained in section 12 of this Act, the State Board may, *suo moto*, whether on the basis of a complaint or otherwise, examine and review any decision of the Registration Authority.
- (4) In the exercise of its functions under this Act, the State Board shall give such directions or pass such orders as are necessary, with reasons to be recorded in writing.

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

- (1) Before appointing any person as the Chairperson or other member, the appropriate Government shall satisfy itself that the person's integrity is such that his / her professional interest shall not affect prejudicially his functions as such member.
- (2) The Chairperson and every other Member shall hold office for such period, not exceeding five years, as may be specified by the appropriate government in the order of his appointment, but shall be eligible for re-appointment.

- (3) Notwithstanding anything contained in sub-section (1) of this section, a member may by writing under his / her hand and addressed to the appropriate Government resign his / her office at any time;
- (4) A vacancy caused by the resignation or removal of the Chairperson or any other member shall be filled by fresh appointment.
- (5) In the event of the occurrence of a vacancy in the office of the Chairperson by reason of his / her death, resignation or otherwise, such one of the members as the appropriate Government may, by notification, authorise in this behalf, shall act as the Chairperson till the date on which a new Chairperson, appointed in accordance with the provisions of this Act to fill such vacancy, takes charge of the office.
- (6) When the Chairperson is unable to discharge his / her functions owing to absence, illness or any other cause, the Vice Chairperson shall discharge the function of the Chairpersons, till the date on which the Chairperson resumes his duties.
- (7) The salaries and allowances payable to and the other terms and conditions of service of the Chairperson and other members shall be such as may be prescribed: provided that neither the salary and allowances nor the other terms and conditions of service of the Chairperson or any other member shall be varied to his disadvantage after his appointment.
- (8) The Chairperson and every other member shall, before entering upon his / her office make a declaration of fidelity and secrecy in the form set out in the Schedule.
- (9) The Chairperson ceasing to hold office as such shall not hold any appointment or be connected with the management or administration in any company, hospital, clinic, society, trust or other undertaking in relation to which any matter has been the subject matter of consideration before the State Board, for a period of three years from the date on which he ceases to hold such office.

10. Procedure of State Boards –

- (1) Subject to the provisions of this Act, the State Board shall have powers to –
 - (a) regulate the procedure and conduct of the business;
 - (b) delegate its powers or functions to such persons or authorities as prescribed in the rules or regulations made under this Act.
- (2) The State Boards shall, for the purposes of any inquiry or for any other purpose under this Act, have the powers to –

- (a) summon and enforce the attendance of any witness and examine him / her on oath;
- (b) order the discovery and production of document or other material objects producible as evidence;
- (c) receive evidence on affidavit;
- (d) requisition any public record from any court or office;
- (e) issue any order for the examination of witnesses;
- (f) any other matter which may be prescribed.

11. Constitution and functions of the Registration Authority –

- (1) The State Government shall constitute the Registration Authority as per the advise of the State Board, within a period of three months of the advise.
- (2) The Registration Authority shall have a full-time Chairman of the level of a Secretary to the State Government, who shall be a recognised expert in assisted reproductive technology or a related field.
- (3) The other members of the Registration Authority shall be part-time members, and shall be adequately compensated for their services.
- (4) Before appointing any member of the Registration Authority, the Government shall satisfy itself that his / her integrity is such that his / her professional interest shall not affect prejudicially his / her functions as a member.
- (5) The Registration Authority shall be provided by the State Government with adequate supporting staff and secretarial assistance, and suitable accommodation.
- (6) The Registration Authority shall issue an appropriate letter granting or rejecting registration to an assisted reproductive technology clinic.

12. Proceedings before State Boards to be judicial proceedings –

- (1) Every State Board shall be deemed to be a civil court and when any offence as is described in this Act is committed in the view or presence of the State Board, the State Board may, after recording the facts constituting the offence and the statement of the accused as provided for in the Code of Criminal Procedure, 1973, forward the case to a Magistrate having jurisdiction to try the same, and the Magistrate to whom any such case is forwarded shall proceed to hear the complaint against the accused as if the case has been forwarded to him under section 346 of the Code of Criminal Procedure, 1973.

- (2) Every proceeding before a State Board shall be deemed to be a judicial proceeding within the meaning of sections 193 and 228, and for the purposes of section 196 of the Indian Penal Code, and the Board shall be deemed to be a civil court for all the purposes of section 195 and Chapter XXVI of the Code of Criminal Procedure, 1973.

CHAPTER - III

PROCEDURES FOR REGISTRATIONS AND COMPLAINTS

13. Registration and accreditation of clinics –

- (1) All assisted reproductive technology clinics shall, within such period and in such form and manner as may be prescribed, register themselves with the Registration Authority.
- (2) An application for registration by an assisted reproductive technology clinic under sub-section (1) of this section shall contain the particulars of the applicant including all details of techniques and procedures of assisted reproductive technology practiced at such clinic.
- (3) The State Board may, subject to such terms and conditions as may be prescribed, register any assisted reproductive technology clinic on the basis of the techniques and procedures of assisted reproductive technology practiced at such clinic, such as –
 - (a) infertility treatment, including Intra-Uterine Insemination (IUI), Artificial Insemination with Husband's semen (AIH), and Artificial Insemination using Donor Semen (AID), involving the use of donated or collected gametes;
 - (b) infertility treatment involving the use and creation of embryos outside the human body;
 - (c) processing or storage of embryos;
 - (d) research.
- (4) Notwithstanding anything contained in this Act or any of the Rules made thereunder, no assisted reproductive technology clinic performing any of the functions under sub-section (3) of this section, or any other advanced diagnostic, therapeutic or research functions, shall practice any aspect of such diagnosis, therapy or research without a certificate of accreditation issued by the State Board.
- (5) The practice of any aspect of assisted reproductive technology in contravention of the provisions of this section shall constitute an offence under this Act.
- (6) Assisted reproductive technology clinics registered under this Act shall be deemed to have satisfied the provisions of the PC & PNDT Act, 1994 [amended in 2002], and shall not be required to seek a separate registration under the said Act.

14. Who may apply for registration –

- (1) Assisted reproductive technology clinics, ART banks and research organizations using human embryos, operative on the date of notification of this Act, shall obtain a temporary registration within six months of the notification of the State Registration Authority by the State Board, and regular registration within 18 months of the above notification. If an assisted reproductive technology clinic that has applied for temporary registration under this clause to the State Registration Authority does not receive the registration or hear from the above Authority within 60 days of the receipt of the application by the Authority, the clinic would be deemed to have received the temporary registration.
- (2) No assisted reproductive technology clinic, ART bank or research organisation using human embryos, other than the ones specified above, shall practice any aspect of assisted reproductive technology, or carry out any research on or using human embryos, or use any premises for such purposes, without a registration under this Act.
- (3) Any assisted reproductive technology clinic or ART bank or research organisation using human embryos, by whatsoever name called, may apply to the Registration Authority for registration to operate the clinic, ART bank or research organisation in accordance with the procedure and criteria laid down in this Act.
- (4) Every application under sub-section (2) of this section shall be in such form and shall be accompanied by such fee and such documents as may be prescribed by the State Government.

15. Grant of registration –

- (1) The Registration Authority may, if it is satisfied that the criteria specified in the Rules have been met, grant registration to the applicant for a term of three years under such terms and conditions as it thinks fit.
- (2) The Registration Authority shall, within one month of a registration being granted under this section, report such registration to the State Board.
- (3) The State Board shall maintain a record of all registrations applied for and granted under this section.
- (4) No registration shall be granted unless the Registration Authority, or such authorised person or persons acting on its behalf, have inspected the premises of the applicant.

16. Renewal, suspension or revocation of registration –

- (1) The Registration Authority may, on an application made to it in such form and manner as may be prescribed, renew a registration granted under the provisions of this Act with effect from the date of its expiry if it is satisfied that the criteria prescribed in the Schedule continue to be met.
- (2) The Registration Authority may at any time suspend the operation of a registration and call upon the holder of the registration to produce such documents or furnish such evidence as may be required if it has reasonable grounds to believe that the terms and conditions of the registration have not been met.
- (3) When acting under sub-section (2) of this section, the Registration Authority shall either revoke the registration or continue the registration, as the case may be, after giving the holder of the registration adequate opportunity to be heard.
- (4) The Registration Authority shall inform the concerned State Board of every assisted reproductive technology clinic in respect of which it has granted, renewed, revoked or denied a registration under this Act within one month of such an action being taken.
- (5) The Registration Authority shall be deemed to have granted renewal for three years to the applicant if the applicant does not receive a definitive communication from the Registration Authority regarding the renewal application within sixty days of the receipt of the application in the office of the Registration Authority.

17. Registration Authority to inspect premises – In the exercise of its powers under this Act, the Registration Authority shall have the power to inspect, with or without prior notice on a working day during working hours, any premises or call for any document or material in the discharge of its powers and functions.

18. Applicability to ART banks and research organisations – The provisions of sections 13 to 16, as relevant, shall apply also to ART banks and research organisations using human embryos.

19. Appeal to the State Board –

- (1) Any person aggrieved by the decision of the Registration Authority made under this Act may, within such period and in such manner and form as may be prescribed, prefer an appeal to the State Board.
- (2) On receipt of an appeal under sub-section (1) of this section, the State Board may, after giving an opportunity to the appellant to be heard, and after making such further inquiry as it thinks fit, confirm, modify or set aside the decision of the Registration Authority, within three months of the receipt of the appeal.

CHAPTER - IV

DUTIES OF AN ASSISTED REPRODUCTIVE TECHNOLOGY CLINIC

20. General duties of assisted reproductive technology clinics –

- (1) Assisted reproductive technology clinics shall ensure that patients, donors of gametes and surrogate mothers are eligible to avail of assisted reproductive technology procedures under the criteria prescribed by the rules under this Act and that they have been medically tested for such diseases, sexually transmitted or otherwise, as may be prescribed and all other communicable diseases which may endanger the health of the parents, or any one of them, surrogate or child.
- (2) It shall be the responsibility of an assisted reproductive technology clinic to obtain, from ART bank(s), all relevant information, other than the name, personal identity and address, of possible gamete donors, and assist the couple or individual desirous of the donation, to choose the donor.
- (3) When an ART bank receives a request from an assisted reproductive technology clinic for a donor oocyte, a responsible member of the staff of the ART bank will accompany the particular donor to the assisted reproductive technology clinic, and obtain a written agreement from the authority designated for this purpose by the clinic, that the clinic shall, under no circumstances (except when asked by a court of law), reveal the identity of the donor to the recipient couple or individual or to anyone else; the clinic shall also ensure that all its staff is made aware of the fact that any step leading to disclosure of the identify (i.e., name and address) to the recipient couple or individual or to anyone else, shall amount to an offence punishable under this Act.
- (4) Either of the parties seeking assisted reproductive technology treatment or procedures shall be entitled to specific information in respect of donor of gametes including, but not restricted to, height, weight, ethnicity, skin colour, educational qualifications, medical history of the donor, provided that the identity, name and address of the donor is not made known.
- (5) Assisted reproductive technology clinics shall obtain donor gametes from ART banks that have ensured that the donor has been medically tested for such diseases, sexually transmitted or otherwise, as may be prescribed and all other communicable diseases which may endanger the health of the parents, or any one of them, surrogate or child.
- (6) Assisted reproductive technology clinics shall provide professional counselling to patients or individuals about all the implications and chances of success of assisted reproductive technology procedures in the clinic and in India and internationally, and shall also inform patients

and individuals of the advantages, disadvantages and cost of the procedures, their medical side effects, risks including the risk of multiple pregnancy, the possibility of adoption, and any such other matter as may help the couple or individual arrive at a decision that would be most likely to be the best for the couple or individual.

- (7) Assisted reproductive technology clinics shall make couples or individuals, as the case may be, aware of the rights of a child born through the use of assisted reproductive technology.
- (8) Assisted reproductive technology clinics shall explain to couples or individuals, as the case may be, the choice or choices of treatment available to them and the reason or reasons of the clinic for recommending a particular treatment, and shall clearly explain the advantages, disadvantages, limitations and cost of any recommended or explained treatment or procedure.
- (9) Assisted reproductive technology clinics shall ensure that information about clients, donors and surrogate mothers is kept confidential and that information about assisted reproductive technology treatment shall not be disclosed to anyone other than a central database to be maintained by the Department of Health Research, except with the consent of the person or persons to whom the information relates, or in a medical emergency at the request of the person or persons or the closest available relative of such person or persons to whom the information relates, or by an order of a court of competent jurisdiction.
- (10) No assisted reproductive technology clinic shall consider conception by surrogacy for patients for whom it would normally be possible to carry a baby to term. Provided that where it is determined that unsafe or undesirable medical implications of such conception may arise, the use of surrogacy may be permitted.
- (11) Assisted reproductive technology clinics shall provide to couples or individuals, as the case may be, a pre-stamped self-addressed envelope to inform the clinic of the results of the assisted reproductive technology procedure performed for the couple or the individual.
- (12) No assisted reproductive technology clinic shall obtain or use sperm or oocyte donated by a relative or known friend of either of the parties seeking assisted reproductive technology treatment or procedures.
- (13) Every assisted reproductive technology clinic shall establish a mechanism to look into complaints in such manner as may be prescribed.
- (14) No assisted reproductive technology procedure shall be performed on a woman below 21 years of age, and any contravention of this stipulation shall amount to an offence punishable under this Act.

- (15) All assisted reproductive technology clinics shall issue to the infertile couple / individual a discharge certificate stating details of the assisted reproductive technology procedure(s) performed on the couple / individual.
- (16) Only a registered ART bank (and no other organization) shall be authorised to advertise for, procure or provide semen, oocyte donor or surrogate mother.

21. Duty of the assisted reproductive technology clinic to obtain written consent –

- (1) No assisted reproductive technology clinic shall perform any treatment or procedure of assisted reproductive technology without the consent in writing of all the parties seeking assisted reproductive technology to all possible stages of such treatment or procedures including the freezing of embryos.
- (2) No assisted reproductive technology clinic shall freeze any human embryos without specific instructions and consent in writing from all the parties seeking assisted reproductive technology in respect of what should be done with the gametes or embryos in case of death or incapacity of any of the parties.
- (3) No assisted reproductive technology clinic shall use any human reproductive material to create an embryo or use an in vitro embryo for any purpose without the specific consent in writing of all the parties to whom the assisted reproductive technology relates.
- (4) The consent of any of the parties obtained under this section may be withdrawn at any time before the embryos or the gametes are transferred to the concerned woman's uterus.

22. Duty of the assisted reproductive technology clinic to keep accurate records –

- (1) All assisted reproductive technology clinics shall maintain detailed records, in such manner as may be prescribed, of all donor oocytes, sperm or embryos used, the manner and technique of their use, and the individual or couple or surrogate mother, in respect of whom it was used.
- (2) All assisted reproductive technology clinics will, as and when such central facilities are established, put on line all information available to them in regard to progress of the patient (such as biochemical and clinical pregnancy) within seven days of the information being available, withholding the identity of the patient.
- (3) Records maintained under sub-section (1) of this section shall be maintained for at least a period of ten years, upon the expiry of which

the assisted reproductive technology clinic shall transfer the records to a central database of a, national ART registry to be set up by the Department of Health Research at the Hqrs of the ICMR.

- (4) In the event of the closure of any assisted reproductive technology before the expiry of the period of ten years under sub-section (2) of this section, the assisted reproductive technology clinic or ART bank shall immediately transfer the records to a central database of a, national ART registry to be set up by the Department of Health Research at the Hqrs of the ICMR

23. Duties of assisted reproductive technology clinics using gametes and embryos –

- (1) Assisted reproductive technology clinics shall harvest oocytes in accordance with such regulations of the National Board or concerned State Board or any rule as may be prescribed under this Act.
- (2) The number of oocytes or embryos that may be placed in a woman in any one cycle shall be according to the rules and regulations provided under this Act.
- (3) No woman should be treated with gametes or embryos derived from the gametes of more than one man or woman during any one treatment cycle.
- (4) An assisted reproductive technology clinic shall never mix semen from two individuals before use.
- (5) Where a multiple pregnancy occurs as a result of assisted reproductive technology, the concerned assisted reproductive technology clinic shall inform the patient immediately of the multiple pregnancy and its medical implications and may carry out foetal reduction after appropriate counselling.
- (6) The collection of gametes from a person whose death is imminent shall only be permissible if such person's spouse intends to avail assisted reproductive technology to have a child.
- (7) No assisted reproductive technology clinic shall use ova that are derived from a foetus, in any process of in vitro fertilisation.
- (8) No assisted reproductive technology clinic shall utilise any semen, whether from an ART bank or otherwise, for any aspect of assisted reproductive technology unless such semen is medically analysed in such manner as may be prescribed.
- (9) Any contravention of stipulation under sub-section 3, 4, 7 and 8 of this section shall amount to an offence under this Act.

24. Pre-implantation Genetic Diagnosis –

- (1) Pre-implantation Genetic Diagnosis shall be used only to screen the embryo for known, pre-existing, heritable or genetic diseases or as specified by the Registration Authority.
- (2) Destruction or donation (with the approval of the patient) to an approved research laboratory for research purposes, of an embryo after Pre-implantation Genetic Diagnosis, shall be done only when the embryo suffers from pre-existing, heritable, life-threatening or genetic diseases
- (3) The State Board may lay down such other conditions as it deems fit in the interests of Pre-implantation Genetic Diagnosis.

25. Sex selection –

- (1) No assisted reproductive technology clinic shall offer to provide a couple with a child of a pre-determined sex.
- (2) It shall be a criminal offence and it is prohibited for anyone to do any act, at any stage, to determine the sex of the child to be born through the process of assisted reproductive technology.
- (3) No person shall knowingly provide, prescribe or administer any thing that would ensure or increase the probability that an embryo shall be of a particular sex, or that would identify the sex of an in vitro embryo, except to diagnose, prevent or treat a sex-linked disorder or disease.
- (4) No assisted reproductive technology clinic will carry out any assisted reproductive technology procedure to separate, or yield fractions enriched in sperm of X or Y variations.
- (5) Any contravention of stipulation under sub-section 1, 2, 3 and 4 of this section shall amount to an offence under this Act.

CHAPTER - V

SOURCING, STORAGE, HANDLING AND RECORD KEEPING FOR GAMETES, EMBRYOS AND SURROGATES

26. Sourcing of gametes –

- (1) The screening of gamete donors and surrogates; the collection, screening and storage of semen; and provision of oocyte donor and surrogates, shall be done by an ART bank registered as an independent entity under the provisions of this Act.
- (2) An ART bank shall operate independently of any assisted reproductive technology clinic.
- (3) ART banks shall obtain semen from males between twenty one years of age and forty five years of age, both inclusive, and arrange to obtain oocytes from females between twenty one years of age and thirty five years of age, both inclusive, and examine the donors for such diseases, sexually transmitted or otherwise, as may be prescribed, and all other communicable diseases which may endanger the health of the parents, or any one of them, surrogate or child.
- (4) All ART banks shall have standard, scientifically established facilities and defined standard operating procedures for all its scientific and technical activities.
- (5) All ART banks shall cryo-preserve sperm donations for a quarantine period of at least six months before being used and, at the expiry of such period, the ART bank shall not supply the sperm to any assisted reproductive technology clinic unless the sperm donor is tested for such diseases, sexually transmitted or otherwise, as may be prescribed.
- (6) An ART bank may advertise for gamete donors and surrogates, who may be compensated financially by the bank.
- (7) An ART bank shall not supply the sperm of a single donor for use more than seventy five times.
- (8) No woman shall donate oocytes more than six times in her life, with not less than a three-month interval between the oocyte pick-ups.
- (9) Eggs from one donor can be shared between two recipients only, provided that at least seven oocytes are available for each recipient.

- (10) All unused oocytes would be either appropriately preserved by the assisted reproductive technology clinic for use on the same recipient(s), or given for research to a bonafide organisation.
- (11) One sample of semen supplied by an ART bank shall be used by the assisted reproductive technology clinic only once on only one recipient.
- (12) An ART bank shall obtain all necessary information in respect of a sperm or oocyte donor or a surrogate, including the name, identity and address of such donor or surrogate, in such manner as may be prescribed, and shall undertake in writing to the donor to keep such information confidential.
- (13) No ART bank shall divulge the name, identity or address of any sperm or oocyte donor to any person or assisted reproductive technology clinic except in pursuance of an order or decree of a court of competent jurisdiction.
- (14) Any person or ART bank who divulges the name, identity or address of a sperm donor in contravention of subsections 11 and 12 of this section shall be guilty of an offence under this Act.
- (15) An ART bank may, for such appropriate fee as may be prescribed, store any semen obtained from a donor for the exclusive use of the wife or partner of the donor.

27. Storage and handling of gametes and embryos –

- (1) The highest possible standards should be followed in the storage and handling of gametes and embryos in respect of their security, and with regard to their recording and identification.
- (2) No donor gamete shall be stored for a period of more than five years.
- (3) An embryo may, for such appropriate fee as may be prescribed, be stored for a maximum period of five years and at the end of such period such embryo shall be allowed to perish or donated to an approved research organization for research purposes with the consent of the patients. If during the period of five years, one of the commissioning partners dies, the surviving partner can use the embryo for herself or for her partner, provided an appropriate consent was taken earlier.

Provided that where the persons to whom such embryo relates fails to pay the fee, or both the commissioning persons die, the assisted reproductive technology clinic may, subject to such regulations as may be prescribed, destroy the embryo or transfer the embryo to any accredited research organisation under section 18 of this Act.

28. Records to be maintained by the ART bank –

- (1) The ART bank shall keep a record of all the gametes received, stored and supplied, and details of the use of the gametes of each donor.
- (2) The records shall be maintained for at least ten years, after which the records shall be transferred to a central database of the Department of Health Research, Government of India.
- (3) Where an ART bank closes before the expiry of the ten year period, the records shall be immediately transferred to the central database of the Department of Health Research, Government of India.
- (4) If not otherwise ordered by a court of competent jurisdiction, all ART banks shall ensure that all information about clients and donors is kept confidential and that information about gamete donation shall not be disclosed to anyone other than the central database of the Department of Health Research.

29. Restriction on sale of gametes, zygotes and embryos –

- (1) The sale, transfer or use of gametes, zygotes and embryos, or any part thereof or information related thereto, directly or indirectly to any party outside India is prohibited and shall be deemed to be an offence under this Act except in the case of transfer of own gametes and embryos for personal use with the permission of the National Board.
- (2) The sale of gametes, except for use by an assisted reproductive technology clinic for treating infertility, and the sale of zygotes and embryos, or of any information related to gametes, zygotes or embryos, within India, is prohibited and shall be deemed to be an offence under this Act.

CHAPTER - VI

REGULATION OF RESEARCH ON EMBRYOS

30. Permission of the Department of Health Research for research –

- (1) The sale of any gametes and embryos or their transfer to any country outside India, for research 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 Department of Health Research.
- (4) Any person or organisation, by whatsoever name called, may apply to the Department of Health Research 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 Department of Health Research may prescribe, and the applicant shall be bound by such terms and conditions as it thinks fit.
- (6) The Department of Health Research 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 Department of Health Research 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.

31. Regulation of research –

- (1) In exercising its powers under this Chapter, the Department of Health Research shall ensure that –

- (a) no research is conducted on any human embryo unless such research is necessary in public interest;
 - (b) no research is conducted on any human embryo created *in vitro* unless such research is necessary in public interest to acquire further scientific knowledge;
 - (c) no research is conducted on any human embryo, other than embryos given for storage to an ART bank under sub-section (3) of section 27, unless full and informed consent in writing is obtained from the persons from whom such embryo was created;
 - (d) no advertisement is issued, and no purchase, sale or transfer is made, of any human embryo created *in vitro* or any part thereof, except in accordance with this Act;
 - (e) no human embryo *created in vitro* is maintained for a period exceeding fourteen days or such other period as recommended by the National Advisory Board;
 - (f) no work is done leading to human reproductive cloning;
 - (g) such other terms and conditions that may be prescribed by the ICMR, are adhered to.
- (2) Any assisted reproductive technology clinic or other research institution or person conducting any research in contravention of the provisions of this Act or any rules or regulations prescribed hereunder shall be an offence under this Act.

CHAPTER - VII

RIGHTS AND DUTIES OF PATIENTS, DONORS, SURROGATES AND CHILDREN

32. Rights and duties of patients –

- (1) Subject to the provisions of this Act and the rules and regulations made thereunder, assisted reproductive technology shall be available to all persons including single persons, married couples and unmarried couples.
- (2) In case assisted reproductive technology is used by a married or unmarried couple, there must be informed consent from both the parties.
- (3) The parents of a minor child have the right to access information about the donor, other than the name, identity or address of the donor, or the surrogate mother, when and to the extent necessary for the welfare of the child.
- (4) All information about the patients shall be kept confidential and information about assisted reproductive technology procedures done on them shall not be disclosed to anyone other than the central depository of the Department of Health Research, except with the consent of the person or persons to whom the information relates, or by a court order.

33. Rights and duties of donors –

- (1) Subject to the other provisions of this Act, all information about the donors shall be kept confidential and information about gamete donation shall not be disclosed to anyone other than the central database of the Department of Health Research, except with the consent of the person or persons to whom the information relates, or by an order of a court of competent jurisdiction.
- (2) Subject to the other provisions of this Act, the donor shall have the right to decide what information may be passed on and to whom, except in the case of an order of a court of competent jurisdiction.
- (3) A donor shall relinquish all parental rights over the child which may be conceived from his or her gamete.
- (4) No assisted reproductive technology procedure shall be conducted on or in relation to any gamete of a donor under this Act unless such donor has obtained the consent in writing of his or her spouse, if there, to such procedure.
- (5) The identity of the recipient shall not be made known to the donor.

34. Rights and duties in relation to surrogacy –

- (1) Both the couple or individual seeking surrogacy through the use of assisted reproductive technology, and the surrogate mother, shall enter into a surrogacy agreement which shall be legally enforceable.
- (2) All expenses, including those related to insurance if available, of the surrogate related to a pregnancy achieved in furtherance of assisted reproductive technology shall, during the period of pregnancy and after delivery as per medical advice, and till the child is ready to be delivered as per medical advice, to the biological parent or parents, shall be borne by the couple or individual seeking surrogacy.
- (3) Notwithstanding anything contained in sub-section (2) of this section and subject to the surrogacy agreement, the surrogate mother may also receive monetary compensation from the couple or individual, as the case may be, for agreeing to act as such surrogate.
- (4) A surrogate mother shall relinquish all parental rights over the child.
- (5) No woman less than twenty one years of age and over thirty five years of age shall be eligible to act as a surrogate mother under this Act.

Provided that no woman shall act as a surrogate for more than five successful live births in her life, including her own children.

- (6) Any woman seeking or agreeing to act as a surrogate mother shall be medically tested for such diseases, sexually transmitted or otherwise, as may be prescribed, and all other communicable diseases which may endanger the health of the child, and must declare in writing that she has not received a blood transfusion or a blood product in the last six months.
- (7) Individuals or couples may obtain the service of a surrogate through an ART bank, which may advertise to seek surrogacy provided that no such advertisement shall contain any details relating to the caste, ethnic identity or descent of any of the parties involved in such surrogacy. No assisted reproductive technology clinic shall advertise to seek surrogacy for its clients.
- (8) A surrogate mother shall, in respect of all medical treatments or procedures in relation to the concerned child, register at the hospital or such medical facility in her own name, clearly declare herself to be a surrogate mother, and provide the name or names and addresses of the person or persons, as the case may be, for whom she is acting as a surrogate, along with a copy of the certificate mentioned in clause 17 below.
- (9) If the first embryo transfer has failed in a surrogate mother, she may, if she wishes, decide to accept on mutually agreed financial terms, at

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

- (10) The birth certificate issued in respect of a baby born through surrogacy shall bear the name(s) of individual / individuals who commissioned the surrogacy, as parents.
- (11) The person or persons who have availed of the services of a surrogate mother shall be legally bound to accept the custody of the child / children irrespective of any abnormality that the child / children may have, and the refusal to do so shall constitute an offence under this Act.
- (12) Subject to the provisions of this Act, all information about the surrogate shall be kept confidential and information about the surrogacy shall not be disclosed to anyone other than the central database of the Department of Health Research, except by an order of a court of competent jurisdiction.
- (13) A surrogate mother shall not act as an oocyte donor for the couple or individual, as the case may be, seeking surrogacy.
- (14) No assisted reproductive technology clinic shall provide information on or about surrogate mothers or potential surrogate mothers to any person.
- (15) Any assisted reproductive technology clinic acting in contravention of sub-section 14 of this section shall be deemed to have committed an offence under this Act.
- (16) In the event that the woman intending to be a surrogate is married, the consent of her spouse shall be required before she may act as such surrogate.
- (17) A surrogate mother shall be given a certificate by the person or persons who have availed of her services, stating unambiguously that she has acted as a surrogate for them.
- (18) A relative, a known person, as well as a person unknown to the couple may act as a surrogate mother for the couple/ individual. In the case of a relative acting as a surrogate, the relative should belong to the same generation as the women desiring the surrogate.
- (19) A foreigner or foreign couple not resident in India, or a non-resident Indian individual or couple, seeking surrogacy in India shall appoint a local guardian who will be legally responsible for taking care of the surrogate during and after the pregnancy as per clause 34.2, till the child / children are delivered to the foreigner or foreign couple or the

local guardian. Further, the party seeking the surrogacy must ensure and establish to the assisted reproductive technology clinic through proper documentation (a letter from either the embassy of the Country in India or from the foreign ministry of the Country, clearly and unambiguously stating that (a) the country permits surrogacy, and (b) the child born through surrogacy in India, will be permitted entry in the Country as a biological child of the commissioning couple/individual) that the party would be able to take the child / children born through surrogacy, including where the embryo was a consequence of donation of an oocyte or sperm, outside of India to the country of the party's origin or residence as the case may be. If the foreign party seeking surrogacy fails to take delivery of the child born to the surrogate mother commissioned by the foreign party, the local guardian shall be legally obliged to take delivery of the child and be free to hand the child over to an adoption agency, if the commissioned party or their legal representative fails to claim the child within one months of the birth of the child. During the transition period, the local guardian shall be responsible for the well-being of the child. In case of adoption or the legal guardian having to bring up the child, the child will be given Indian citizenship.

- (20) A couple or an individual shall not have the service of more than one surrogate at any given time.
- (21) A couple shall not have simultaneous transfer of embryos in the woman and in a surrogate.
- (22) Only Indian citizens shall have a right to act as a surrogate, and no ART bank/ART clinics shall receive or send an Indian for surrogacy abroad.
- (23) Any woman agreeing to act as a surrogate shall be duty-bound not to engage in any act that would harm the foetus during pregnancy and the child after birth, until the time the child is handed over to the designated person(s).
- (24) The commissioning parent(s) shall ensure that the surrogate mother and the child she deliver are appropriately insured until the time the child is handed over to the commissioning parent(s) or any other person as per the agreement and till the surrogate mother is free of all health complications arising out of surrogacy.

35. Determination of status of the child –

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

- (2) A child born to an unmarried couple through the use of assisted reproductive technology, with the consent of both the parties, shall be the legitimate child of both parties.
- (3) In the case of a single woman the child will be the legitimate child of the woman, and in the case of a single man the child will be the legitimate child of the man.
- (4) In case a married or unmarried couple separates or gets divorced, as the case may be, after both parties consented to the assisted reproductive technology treatment but before the child is born, the child shall be the legitimate child of the couple.
- (5) A child born to a woman artificially inseminated with the stored sperm of her dead husband shall be considered as the legitimate child of the couple.
- (6) If a donated ovum contains ooplasm from another donor ovum, both the donors shall be medically tested for such diseases, sexually transmitted or otherwise, as may be prescribed, and all other communicable diseases which may endanger the health of the child, and the donor of both the ooplasm and the ovum shall relinquish all parental rights in relation to such child.
- (7) The birth certificate of a child born through the use of assisted reproductive technology shall contain the name or names of the parent or parents, as the case may be, who sought such use.
- (8) If a foreigner or a foreign couple seeks sperm or egg donation, or surrogacy, in India, and a child is born as a consequence, the child, even though born in India, shall not be an Indian citizen.

36. Right of the child to information about donors or surrogates –

- (1) A child may, upon reaching the age of 18, ask for any information, excluding personal identification, relating to the donor or surrogate mother.
- (2) The legal guardian of a minor child may apply for any information, excluding personal identification, about his / her genetic parent or parents or surrogate mother when required, and to the extent necessary, for the welfare of the child.
- (3) Personal identification of the genetic parent or parents or surrogate mother may be released only in cases of life threatening medical conditions which require physical testing or samples of the genetic parent or parents or surrogate mother.

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

CHAPTER - VIII

OFFENCES AND PENALTIES

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

- (1) No assisted reproductive technology clinic shall issue or cause to be issued any advertisement in any manner regarding facilities of pre-natal determination of sex.
- (2) No assisted reproductive technology clinic, or agent thereof, shall publish or distribute or cause to be published or distributed any advertisement in any manner regarding facilities of pre-natal determination of sex.
- (3) Any person who contravenes the provisions of this section shall be punishable with imprisonment for a term which may extend to five years and with fine which may be specified.

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

38. Offences and penalties –

- (1) Any medical geneticist, gynaecologist, registered medical practitioner or any person who owns or operates any assisted reproductive technology clinic, or is employed in such a facility and renders his professional or technical services to such facility, whether on an honorary basis or otherwise, and who contravenes any of the provisions of this Act or rules made thereunder, shall be punishable with imprisonment for a term which may extend to three years and / or with fine which may be specified, and on any subsequent conviction, with imprisonment which may extend to five years and / or fine which may be specified.
- (2) The name of the registered medical practitioner who has been convicted by the court under sub-section 1 of this section shall be reported by the State Board to the respective State Medical Council for taking necessary action including the removal of his name from the register or the Council for a period of two years for the first offence and permanently for any subsequent offence.
- (3) Any person who seeks the aid of assisted reproductive technology or of a medical geneticist, gynaecologist or registered medical practitioner for conducting pre-natal diagnostic techniques on any pregnant woman for purposes other than those specified in clause (2) of section 4 of the Pre-natal Diagnostic Techniques (Regulation and Prevention of

Misuse) Act, 1994 [Act 57 of 1994], shall be punishable with imprisonment for a term which may extend to three years and with fine which may be specified, and on any subsequent conviction with imprisonment which may extend to five years and with fine which may be specified.

- (4) The transfer of a human embryo into a male person or into an animal that is not of the human species shall be an offence under this Act and shall be punishable with imprisonment for a term which may extend to three years and with fine which may be specified.
- (5) The sale of any embryo for research is absolutely prohibited and shall be an offence under this Act punishable by imprisonment for a term which may extend to three years and with fine which may be specified.
- (6) Use of individual brokers or paid intermediaries to obtain gamete donors or surrogates shall be an offence under this Act, punishable by imprisonment for a term which may extend to three years and fine which may be specified.

39. Presumption in the case of conduct of pre-natal diagnostic techniques – Notwithstanding anything in the Indian Evidence Act, 1872, the court shall presume, unless the contrary is proved, that the pregnant woman has been compelled by her husband or the relative to undergo pre-natal diagnostic technique.

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

41. Offences by companies –

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

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

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

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

Explanation – For the purposes of this section,

(a) “company” means any body corporate and includes a firm or other association of individuals, and

(b) “director”, in relation to a firm, means a partner in the firm.

42. Offence to be cognizable – Every offence under this Act shall be cognizable.

CHAPTER - IX

MISCELLANEOUS

43. Maintenance of records –

- (1) All records, charts, forms, reports, consent letters and all other documents required to be maintained under this Act and the rules shall be preserved for a period of ten years or for such period as may be prescribed

Provided that, if any criminal or other proceedings are instituted against any facility using assisted reproductive technology, the records and all other documents of such facility shall be preserved till the final disposal of such proceedings.

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

44. Power to search and seize records etc. –

- (1) If the State Board has reason to believe that an offence under this Act has been or is being committed at any facility using assisted reproductive technology, such Board or any officer authorised thereof in this behalf may, subject to such rules as may be prescribed, enter and search at all reasonable times with such assistance, if any, as such authority or officer considers necessary, such facility, and examine any record, register, document, book, pamphlet, advertisement or any other material object found therein and seize the same if the State Board or officer has reason to believe that it may furnish evidence of the commission of an offence punishable under this Act.
- (2) The provisions of the Code of Criminal Procedure, 1973, relating to searches and seizures shall, so far as may be, apply to every search or seizure made under this Act.

45. Power to remove difficulties –

- (1) If any difficulty arises in giving effect to the provisions of this Act, the Central Government may, by order published in the Official Gazette, make such provisions not inconsistent with the provisions of this Act as may appear to be necessary for removing the difficulty:

Provided that no order shall be made under this section after the expiry of three years from the commencement of this Act.

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

- 46. Protection of action taken in good faith** – No suit, prosecution or other legal proceeding shall lie against the Central or the State Government or the National Board or State Boards or Registration Authority or any officer authorised by any of them, for anything which is in good faith done or intended to be done in pursuance of the provisions of this Act.
- 47. Power to make regulations** – The National Advisory Board may, with the previous sanction of the Central Government, by notification in the Official Gazette, make regulations not inconsistent with the provisions of this Act and the rules made thereunder, to provide for –
- (a) the time and place of the meetings of the Board and the procedure to be followed for the transaction of business at such meetings, and the number of members which shall form the quorum;
 - (b) the conditions for the transfer of embryos and gametes to research institutions;
 - (c) regulation of Pre-implantation Genetic Diagnosis;
 - (d) research on embryos;
 - (e) the efficient conduct of the affairs of the Board;
 - (f) any other purpose that may be prescribed.
- 48. Power of the Central Government to make rules** –
- (1) The Central Government may make rules for carrying out the provisions of this Act.
 - (2) In particular, and without prejudice to the generality of the foregoing power, such rules may provide for –
 - (a) categories of assisted reproductive technology clinics;
 - (b) the minimum requirements regarding staff in assisted reproductive technology clinics;
 - (c) the minimum physical infrastructure requirements for an assisted reproductive technology clinic;
 - (d) the various assisted reproductive technology procedures to be adopted by an assisted reproductive technology clinic;
 - (e) the criteria for selecting patients for an assisted reproductive technology procedure;

- (f) the criteria for selecting an assisted reproductive technology procedure for a patient;
 - (g) information and advise to, and counselling of patient;
 - (h) the eligibility of couples and individuals to use assisted reproductive technology;
 - (i) the eligibility of donors;
 - (j) the eligibility of surrogate mothers;
 - (k) the number of embryos that can be implanted in a woman;
 - (l) the number of times that a patient can be given a procedure;
 - (m) the maintenance of records;
 - (n) procedure to search and seize;
 - (o) the criteria to be fulfilled for a license;
 - (p) the effective implementation of the Act.
- (3) Every rule made by the Central Government under sub-section (1) of this section shall be laid, as soon as may be after it is made, before each House of Parliament, while it is in session, for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the rule or regulation or both Houses agree that the rule or regulation should not be made, the rule or regulation shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule or regulation.

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

50. Act to have effect in addition to other Acts – The provisions of this Act shall be in addition to, and not in derogation of, the provisions of any other law, for the time being in force, except for the following:

- a) Provision made in Section 13(6) of this Act;
- b) Inapplicability of the provision of the Right to Information Act in regard to provision made in Section 20(9) and 26(13) of this Act.