

**THE
ASSISTED REPRODUCTIVE TECHNOLOGY
(REGULATION) BILL, 2008**

AN ACT

to provide for a national framework for the regulation and supervision of assisted reproductive technology and matters connected therewith or incidental thereto.

BE IT ENACTED by the Parliament in the 58th 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, 2008.
- (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 “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;
- f “cryo-preservation”, means the freezing and storing of gametes, zygotes and embryos;

- g “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;
- h “embryo”, means the fertilized ovum that has begun cellular division and continued development up to the blastocyst stage till the end of five days;
- i “fertilization”, means the penetration of the ovum by the spermatozoon and fusion of genetic materials resulting in the development of a zygote;
- j “foetus”, means the product of conception, starting from completion of embryonic development until birth or abortion;
- k “gamete”, means sperm and oocyte;
- l “gamete donor”, means a person who provides sperm or oocyte with the objective of enabling an infertile couple to have a child;
- m “Indian Council of Medical Research”, means the Indian Council of Medical Research as registered under the Societies Registration Act, 1860;
- n “implantation”, means the attachment and subsequent penetration by the zona-free blastocyst, which starts five to seven days following fertilization;
- o “infertility”, means the inability to conceive after at least one year of unprotected coitus;
- p “oocyte” and “ovum”, mean, respectively, the female gamete present in the ovary, and an ovulated oocyte in which the first polar body has been released;
- q “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;
- r “semen bank”, shall be deemed to include both sperm and oocytes;
- s “sperm”, means the male gametes produced in the testicles and contained in semen ejaculated by a male;
- t “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 to term and hand over the child to the person or persons for whom she is acting as a surrogate;

- u “surrogate mother”, means a woman 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 full term and deliver the child to its biological parent(s);
- v “surrogacy agreement”, means a contract between the person(s) availing of assisted reproductive technology and the surrogate mother;
- w “unmarried couple”, means a man and a woman, both of marriageable age, living together with mutual consent but without getting married;
- x “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) A Chairman to be appointed by the Ministry of Health and Family Welfare;
 - (b) An officer, not below the rank of Joint Secretary from the Indian Council of Medical Research, who shall be the Member-Secretary of this 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 – The National Board and every State Board shall be deemed to be a civil court for the purposes of section 195 and Chapter XXVI of the Code of Criminal Procedure, 1973, and every proceeding before the National Board or every 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, 1860.

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, namely –
 - (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 gametes and embryos;
 - (d) research on embryos.
- (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, semen 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, semen 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 semen bank or research organisation using human embryos, by whatsoever name called, may apply to the Registration Authority for registration to operate the clinic, semen 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, any premises or call for any document or material in the discharge of its powers and functions.

18. Applicability to semen banks and research organisations – The provisions of sections 12 to 16 shall apply also to semen 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 semen 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 a semen bank receives a request from an assisted reproductive technology clinic for a donor oocyte, a responsible member of the staff of the semen 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 semen 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 Indian Council of Medical 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 envelop 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.

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 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, the individual or couple or surrogate mother, in respect of whom it was used, and the deoxyribonucleic acid (DNA) fingerprint of the individual or couple and the child born as a result of assisted reproductive technology treatment or procedures.
- (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 the Indian Council of Medical Research.

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

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) The ART 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 shall, if so instructed by the patient, carry out foetal reduction.
- (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 a semen 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 collection, screening, storage and handling of gametes shall be done by a semen bank registered as an independent entity under the provisions of this Act.
- (2) A semen bank shall operate independently of any assisted reproductive technology clinic.
- (3) Semen 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 semen banks shall have standard, scientifically established facilities and defined standard operating procedures for the cryo-preservation of sperm and oocytes.
- (5) All semen 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 semen 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) A semen bank may advertise for gamete donors and surrogates, who may be compensated financially by the bank.
- (7) A semen 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-months interval between the oocyte pick-ups.
- (9) If more than fourteen (14) oocytes are retrieved from the donor at one occasion, they shall not be used for more than two recipients thus ensuring that at least seven oocytes are available for each recipient.
- (10) One sample of semen supplied by a semen bank shall be used by the ART clinic only once on only one recipient.

- (11) A semen 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.
- (12) No semen bank shall divulge the name, identity or address of any sperm donor to any person or assisted reproductive technology clinic except in pursuance of an order or decree of a court of competent jurisdiction.
- (13) Any person or semen 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.
- (14) A semen 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 gamete shall be stored for a period of more than ten 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.

Provided that where the persons to whom such embryo relates fails to pay the fee, 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 13 of this Act.

28. Records to be maintained by semen bank –

- (1) The semen 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 Indian Council of Medical Research.

- (3) Where an assisted reproductive technology clinic closes before the expiry of the ten year period, the records shall be immediately transferred to the central database of the Indian Council of Medical Research.
- (4) If not otherwise ordered by a court of competent jurisdiction, all semen 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 Indian Council of Medical 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 Indian Council of Medical Research (ICMR) for research –

- (1) The sale of any gametes and embryos for research or their transfer to any country outside India, 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.

31. Regulation of research –

- (1) In exercising its powers under this Chapter, the ICMR 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 a semen 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, ART shall be available to all persons including single persons, married couples and unmarried couples.
- (2) In case ART 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 ART procedures done on them shall not be disclosed to anyone other than the central depository of the ICMR, 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 Indian Council of Medical 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.

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, 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 under twenty one years of age and over forty 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 three successful live births in her life.

- (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 undergone intravenous medical treatment or received a blood transfusion.
- (7) Individuals or couples may obtain the service of a surrogate through a semen bank, or 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 the genetic parents / parent of the baby.
- (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 Indian Council of Medical 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. 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 ART clinic through proper documentation 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.

- (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.

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.

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

- (1) A child may, upon reaching the age of 18, apply for any information, excluding personal identification, relating to his / her genetic parent or parents 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 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.
- (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.

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 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, non-bailable and non-compoundable – Every offence under this Act shall be cognizable, non-bailable and non-compoundable.

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 sale, transfer or hire 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.

**The
Assisted Reproductive Technology
(Regulation) Rules - 2008**

The Assisted Reproductive Technology (Regulation) Rules, 2008

1. Short Title and Commencement

- (1) These rules may be called the Assisted Reproductive Technology (Regulation) Rules, 2008.
- (2) They shall come into force on the date of their publication in the Official Gazette.

2. Definition

In these rules, unless the context otherwise requires:

- (a) 'Act' means the Assisted Reproductive Technology (Regulation) Act, 2008;
- (b) 'form' means a form appended to these rules;
- (c) 'section' means a section of the Act;
- (d) Words and expression used herein and not defined in these rules but defined in the Act, shall have the meaning, respectively, assigned to them in the Act;
- (e) ART means Assisted Reproductive Technology;
- (f) 'Infertility clinics' or 'ART clinics' mean all clinics treating infertility.
- (g) 'Infertility clinics' mean ART clinics and 'ART clinics' mean Infertility clinics.

3. Categories of Infertility / ART Clinics

- (1) The categories of infertility / ART clinics i.e. Primary (Level 1A), Primary (Level 1B), Secondary (Level 2) and Tertiary (Level 3) Infertility / ART Clinics shall be as specified in Schedule I, Part 1.
- (2) Wherever an Institute, Hospital, Nursing Home or any place by whatever name called, provides Infertility / ART services, it shall conform to the requirements as specified in Schedule I, Part-1.

4. Minimum Requirement Regarding Staff in Infertility Clinics

Minimum requirement of staff and their qualification for various types of infertility clinics shall conform to the requirement as specified in Schedule I, Part-2.

5. Minimum Physical Infrastructure Requirement for an Infertility Clinic

Minimum physical infrastructure for infertility clinics shall conform to the requirement as specified in Schedule I, Part-3.

6. ART Procedures

The various ART procedures that have been widely tested and proven to be satisfactory have been specified in Schedule I, Part-4. The ART procedures adopted by the infertility clinic shall conform to the procedures as specified in Schedule I, Part-4.

7. Patient Selection

The criteria for patient selection in order to categorize them in specified groups for referral to different levels of infertility / ART clinics shall conform to the requirement as specified in Schedule I, Part-5.

8. Selection Criteria for ART Procedure

The choice of the procedure to be used shall depend upon the need, resources and circumstances of the individual couple, availability of the facilities, and experience and expertise of the Gynaecologist / Embryologist. The selection criteria for various ART procedures shall conform to the requirement as specified in Schedule I, Part-6.

9. Information, Advice and Counselling to Patients

Information, advice and counselling to be given to the patient shall conform to the requirement as specified in Schedule I, Part-7.

10. Registration of ART Clinics, Semen Banks and Research Centres using Human Embryos

- (1) An application for registration shall be made by the above to the State Registration Authority in duplicate, in Forms A, A1 and A2, respectively.
- (2) The Registration Authority, or any person in its office authorized in this behalf, shall acknowledge receipt of the application for registration, in the acknowledgement slip provided at the bottom of the Form, immediately after delivery at the office of the Appropriate Authority or not later than the next working day if received by post.

11. Application Fee

- (1) Every application for registration under Rule 10 shall be accompanied by an application fee to be prescribed by the State Government.
- (2) The application fee shall be paid by a demand draft drawn in favour of the Registration Authority, on any scheduled bank located at the headquarters of the Registration Authority. The fees collected under Sub-rule (1), shall be deposited by the Registration Authority concerned in a bank account opened in the name of the official designation of the Registration Authority concerned and shall be

utilized by the Registration Authority for activities connected with the implementation of the provisions of the Act and these rules.

12. Certificate of Registration

- (1) The Registration Authority shall, after making such enquiry and after satisfying itself that the applicant has complied with all the requirements, send a certificate of registration, in duplicate, in Form B to the applicant. One copy of the certificate of registration shall be displayed by the registered ART clinic at a conspicuous place at its place of business.
- (2) If, after enquiry and after giving an opportunity of being heard to the applicant, the Registration Authority is satisfied that the applicant has not complied with the requirements of the Act and these rules, it shall, for reasons to be recorded in writing, reject the application for registration and communicate such rejection of the applicant along with the reasons, as specified in Form C.
- (3) In such a case, the applicant would have the right to appeal to the State Board against the decision of the Registration Authority, stating clearly the reasons for making the appeal, within 30 days of receiving the decision of the Registration Authority. The State Board should take a view on the appeal within 60 days of its receipt.
- (4) An enquiry under Sub-rule (1) including inspection at the premises of ART clinic shall be carried out only after due notice is given to the applicant by the Registration Authority.
- (5) Grant of certificate of registration or rejection of application for registration shall be communicated to the applicant in form B or form C as the case may be, within a period of 60 days from the date of receipt of application for registration in the case of clinics in operation on the date of notification of these rules, and 120 days in the case of clinics starting operation after the above notification. If no communication is received from the Registration Authority within the above period, the ART clinic would deem to have been cleared for registration.
- (6) The certification of registration, shall be non-transferable. In the event of change of ownership or on ceasing to function as an ART clinic, both copies of the registration shall be surrendered to the Registration Authority.
- (7) In the event of change of ownership of the ART clinic, the new owner of such clinic shall apply afresh for grant of certificate of registration.

13. Validity of Registration

Every certificate of registration shall be valid for a period of three years from the date of issue.

14. Renewal of Registration

- (1) An application for renewal of certificate of registration shall be made in duplicate in Form A, to the Registration Authority 60 days before the date of expiry of the certificate of registration. Acknowledgement of the receipt of such application shall be issued by the Registration Authority in the manner specified in Sub-rule (2) of Rule 10.
- (2) The Registration Authority shall, after holding an enquiry and after satisfying itself that the applicant has complied with all the requirements of the Act and these rules, renew the certificate of registration, as specified in Form B, for a further period of three years from the date of expiry of the certificate of registration earlier granted.
- (3) If, after enquiry and after giving an opportunity of being heard to the applicant, the Registration Authority is satisfied that the applicant has not complied with the minimum requirement of the Act and these rules itself, it shall, for reasons to be recorded in writing, reject the application for renewal of certificate of registration and communicate such rejection to the applicant as specified in Form C.
- (4) In such a case, the applicant would have the right to appeal to the State Board against the decision of the Registration Authority, stating clearly the reasons for making the appeal, within 30 days of receiving the decision of the Registration Authority. The State Board should take a view on the appeal within 60 days of its receipt.
- (5) The State Government shall prescribe the fee for renewal of certificate of registration.
- (6) On receipt of the renewal of the certificate of registration in duplicate, or on receipt of communication of rejection of the application for renewal, both copies of the earlier certificate of registration shall be surrendered immediately to the Registration Authority by the ART clinic.
- (7) In the event of failure of the Registration Authority to renew the certificate of registration or to communicate rejection of application for renewal of registration within a period of 60 days from the date of receipt of application for renewal of registration, the certificate of registration shall be deemed to have been renewed for three years.

15. Consents, Agreements and Contracts for Conducting ART Procedures

- (1) As prescribed in Section 20 of the Act, the ART clinic shall obtain a written consent from the couple before conducting any ART procedure, as specified in Form D, in a language that the couple understands. The couple's written consent for artificial insemination or intrauterine insemination with husband's semen or sperm shall be taken in Form E. The couple's written consent for artificial insemination or intrauterine

insemination with donor semen or sperm shall be taken in Form F. The couple's written consent for freezing of embryos shall be taken in Form G. The couple's written consent for procedures of PESA and TESA shall be taken in Form H. The couple's written consent for oocyte retrieval / embryo transfer shall be taken in Form I. Agreement of surrogacy shall be signed in Form J. Consent for donation of eggs (oocytes) shall be taken in Form K. Consent for donation of semen / sperm shall be taken in Form L. Information on semen donor, oocyte donor and surrogate mother shall be provided on Form M, M1 and M2, respectively. The results of screening of semen / oocyte donors and surrogate mothers shall be recorded by the semen bank on Form N. Records of use of donor gametes and of surrogate mothers, by an assisted reproductive technology clinic, shall be maintained on Form O. Oocytes shall be harvested and the records maintained in Form P. Semen analysis record shall be maintained as in Form Q. Contracts (including the financial arrangements) between the semen bank on the one hand, and the semen donor, oocyte donor, surrogate mother, patient, or the assisted reproductive technology clinic on the other hand, shall be signed on Form R, R1, R2, S and T, respectively. The contract (including the financial arrangement) between the patient and the surrogate shall be signed on Form U. The oath of fidelity and secrecy by members of the National Advisory Board and the State Boards, and by others where required, shall be on Form V.

- (2) All the State / UT Governments may issue translations of Forms A to V in languages used in the State / UT. Where no official translation in a language understood by the couple seeking treatment is available, the ART Clinic may translate the consent form(s) into a language the couple understands. In the case of illiterate patients, the Counsellor will, directly or through an interpreter, and in the presence of a third party chosen by the patient / couple if so desired by the patient / couple, read out and explain all the contents of the consent form(s) to the patient / couple.
- (3) No ART clinic shall use a technique on a patient for which expertise does not exist with the staff of the Clinic.

16. Facilities for Inspection

Every ART clinic shall afford reasonable facilities for inspection of the place, equipment and records to the Registration Authority or to any other person authorized by the Registration Authority in this behalf. Such an inspection of an already registered clinic may take place without any notice, during the working hours of the clinic.

17. Public Information

At least one copy of the Act and these rules shall be available on the premises of every ART clinic and shall be made available to the clientele on demand for perusal.

SCHEDULE – I
(See Rules 3, 4, 5, 6, 7, 8 & 9)

PART – 1

1. Primary (Level 1A) Infertility Clinics

These clinics will not require registration under the Act. They would be clinics where preliminary investigations are carried out and type and cause of infertility diagnosed. Primary infertility care unit or clinics could be a doctor's consulting room, such as a gynaecologist's or a physician's consulting room, or even a general hospital. Depending on the severity of infertility, the couple could be treated at the Level 1A clinic or referred to a speciality (Level 1B, Level 2 or Level 3) clinic.

The responsibilities of a Level 1A primary infertility clinic will be:

- a) Diligent history taking and basic investigations such as physical examination and semen analysis.
- b) Treatment of minor anatomical defects like imperforate hymen.
- c) Treatment of mild endometriosis after confirming its presence by diagnostic laparoscopy carried out by a competent surgeon with adequate endoscopic experience.
- d) Introduction of ovulation in anovulatory women (especially PCOS) with drugs such as clomiphene citrate, with or without adjuncts like bromocriptine, eltroxin, dexamethasone or spironolactone. (Gonadotropin should not be used at a Level 1A primary infertility clinic.)
- e) Correcting minor endocrine disorders such as thyroid disorders or hyperprolactinemia, by prescribing appropriate corrective medications.
- f) Treatment of oligozoospermia.
- g) Detecting infection of the reproductive tract using appropriate diagnostic tests, followed by normal health-care steps after carrying out appropriate antibiotic sensitivity tests. (Particular care must be taken to treat the couple and not the female or the male patient alone.)
- h) Referral of the couple to Level 1B, Level 2 or Level 3 infertility clinic as appropriate, specially when the woman's age is more than 35, or when the couple has a multifactorial defect, or when patients with single treatable defect have not responded to conventional therapy.

The gynaecologist or the physician in charge of a Level 1A infertility care unit should have an appropriate post-graduate degree or diploma, and be capable of taking care of the above responsibility.

1.1 Primary (Level 1B) Infertility Clinics engaging in artificial insemination using husband's semen (AIH), artificial insemination using donor semen (AID) or intrauterine insemination (IUI) using husband's or donor semen

These clinics will require registration under the Act. They will be required to have, in addition to what has been stated in para 1 above, the facilities mentioned in the following two sub-paras (1.1.1 and 1.1.2). The insemination in such clinics must be done under the supervision of a gynaecologist with a post-graduate degree.

1.1.1. Facilities for investigations:

- a) Immunological tests for infertility, sperm cervical mucous penetration test (SCMPT), sperm cervical mucous test (SCMT), and test for antibodies (IgG, IgA) against sperm antigen in cervical mucous.
- b) Sperm function tests such as hypo-osmotic swelling test (HOST), and assessment for improvement of sperm motility potential with pentoxifylline co-culture.
- c) Assessment of follicular growth and ovulation by serial ultrasonography.
- d) Hysteroscopy, laparoscopy and ultrasonography.

1.1.2. Treatment facilities:

- a) Facilities for semen preparation for IUI, including an appropriate clean room for IUI.

(The facilities for investigation and for semen preparation mentioned above could be shared with another accredited infertility clinic or semen bank or an accredited clinical laboratory.)

1.2 Secondary (Level 2) Infertility Clinics

These clinics will require registration under the Act. They must have infrastructure for further in-depth investigation and extended treatment of infertility except where oocytes are handled outside the body. Some of the investigations and treatment facilities required for Level 2 infertility clinics are mentioned in the following two sub-paras (1.2.1 and 1.2.2).

1.2.1. Facilities for investigations:

- a) Immunological tests for infertility, sperm cervical mucous penetration test (SCMPT), sperm cervical mucous test (SCMT), and tests for antibodies (IgG, IgA) against sperm antigen in cervical mucous which can be outsourced to an accredited clinical laboratory.
- b) Sperm function tests like hypo-osmotic swelling test (HOST), and assessment of the improvement of sperm motility potential with pentoxifylline co-culture.
- c) Assessment of follicular growth and ovulation by serial transvaginal sonography (TVS).
- d) Hysteroscopy, laparoscopy and transvaginal sonography.

1.2.2. Treatment facilities:

- a) Facilities for semen preparation and IUI, including an appropriate clean room for IUI.
- b) Provision for semen collection in men with a vibrator or an electroejaculator in erectile dysfunction and ejaculatory problems.
- c) Conservative surgery either through a laparoscope or hysteroscope, or via laparotomy.
- d) Combined medical-surgical therapy by a co-ordinated team, for example in endometriosis.
- e) Provision for extended treatment of infertility except for oocyte pick up, in vitro fertilization (IVF), intracytoplasmic sperm injection (ICSI), and similar techniques

1.3 Tertiary (Level 3) Infertility Clinics

These clinics will require registration and will have three functions to perform, viz., diagnostic and therapeutic at the highest level of specialization and with the best of facilities, and research. Some examples of the first two functions are given below in sub-paras 1.4.1 to 1.4.3. If any of the facilities mentioned below does not exist in the clinic, the clinic should have access to such a facility in another appropriately accredited clinic, semen bank, or laboratory.

1.3.1 Diagnostic procedures for male infertility:

- a) Endocrine assay.

- b) Further tests for sperm function and integrity such as acrosome reaction and sperm-oocyte interaction in vitro.
- c) Assessment of cell contaminants, debris and infection.
- d) Karyotyping.
- e) Assessment of seminal plasma for viscosity, thinness, blood contamination and biochemical constituents.

1.3.2 Diagnostic procedures for female infertility:

- a) Endocrine assays.
- b) Karyotyping.
- c) Transvaginal sonography.

1.3.3. Therapeutic procedures:

- a) Induction of ovulation using gonadotropin, a GnRH agonist and antagonist, and other adjuvants.
- b) All varieties of assisted reproductive technologies, including ICSI.
- c) Procedures for IUI using split ejaculate, pooled ejaculate or sperm recovered from post-coital specimen of urine in retrograde ejaculation.
- d) Embryo cryopreservation.

PART – 2

2. Minimum Requirement Regarding Staff in Infertility Clinics

The staff requirements given below will be mandatory for Level 2 and Level 3 clinics. In the case of small Level 2 and Level 3 clinics, the services of the Clinical Embryologist, and / or of the Counsellor, may be shared.

2.1. Gynaecologist

The minimal qualification for a gynaecologist in a Level 2 or Level 3 clinic will be a post-graduate degree in gynaecology. Additional experience should include:

- Understanding of the causative factors of male and female infertility.
- Knowledge of the practice and use of diagnostic methods for determining the cause of infertility.
- Knowledge of the clinical aspects of reproductive endocrinology and the reproductive defects caused by endocrine factors, and an understanding of the limitations of the currently used hormone assay methods, and of the techniques available for medically or surgically correcting endocrine disorders.
- Competence in gynaecological ultrasonography to diagnose reproductive tract anomalies; monitoring ovarian and uterine response to ovarian stimulation; picking up oocytes at the most appropriate time; and transferring embryos by any one of the several methods currently available to handle embryo transfer in 'difficult' cases.

The gynaecologist must be knowledgeable about the principles of ovarian stimulation and the management of complications arising thereupon.

The responsibilities of the gynaecologist would include the following:

- Interviewing of the infertile couple initially.
- History taking.
- Physical examination of the female.
- Recommending appropriate tests to be carried out, interpreting them and treating medical disorders (such as infections and endocrine anomalies).
- Carrying out gynaecological endoscopy and ultrasonographic intervention for diagnosis and therapy of infertility.
- Carrying out AIH, AID, IUI, in vitro fertilization (IVF) or intracytoplasmic sperm injection (ICSI), and other ancillary procedures as the case and facilities may warrant, based on diagnostic evidence.

For a level 3 clinic, the gynaecologist must also have the expertise of ovum pick up and embryo transfer.

2.2 Andrologist

Fifty percent of infertility cases are related to male factors, many of which can be treated by specific ART procedures or other less invasive procedures. Andrology, a subject related to male reproduction, does not constitute a formal course in the medical curriculum in India. In

India it is the urologist with a post-graduate degree in urology that often takes on the task of treating male infertility. Such individuals must receive additional training in diagnosis of various types of male infertility covering psychogenic impotence, anatomical anomalies of the penis which disable normal intercourse, endocrine factors that cause poor semen characteristics and / or impotence, infections, and causes of erectile dysfunction.

The andrologist must have knowledge of the occupational hazards, infections and fever that cause reversible or irreversible forms of infertility, and knowledge of ultrasonographic and vasographic studies of the male reproductive tract. He / she must also be well-versed in treating impotence and ejaculatory dysfunction.

He / she must understand the principles of semen analyses and their value and limitation in diagnosis of male fertility status. The andrologist must be able to collect semen by prostatic massage for microbial culture in cases where infection may lie in the upper regions (prostate, seminal vesicles) of the reproductive tract. He / she should also be able to collect spermatozoa through surgical sperm retrieval techniques, and be well-versed in the technique of electro-ejaculation. He must also be knowledgeable about the genetic implications of using poor-quality sperm for ICSI. He / she should be familiar with the surgical procedures available for correcting an anatomical defect in the reproductive system such as epididymovasal re-anastomosis and varicocelectomy.

An individual may act as an andrologist for more than one clinic but each clinic where the andrologist works must own responsibility for the andrologist and ensure that the andrologist is able to take care of the entire work load of the clinic without compromising on the quality of service.

The responsibilities of the andrologist would include the following:

- Recording case histories.
- Prescribing appropriate diagnosis and treatment based on the diagnosis.
- Carrying out such surgical procedures as warranted by the diagnosis.
- Maintaining all the records, from the case history to the treatment given, and the patient consent forms.
- Referring the couple to the gynaecologist for carrying out the appropriate ART procedure if necessary, after the male factor has been duly investigated.
- Referring the couple to the counsellor if necessary.

2.3 Clinical Embryologist

The clinical embryologist must be knowledgeable in mammalian embryology, reproductive endocrinology, genetics, molecular biology, biochemistry, microbiology and in vitro culture techniques. The embryologist must also be familiar with ART. He / she must be either a medical graduate or have a post-graduate degree or a doctorate in an appropriate area of life sciences. (In the case of a clinic in existence for at least one year before the promulgation of these rules, a person with a B.Sc. or B.V.Sc degree but with at least five years of first-hand, hands-on experience of the techniques mentioned below and of discharging the responsibilities listed below, would be acceptable for functioning as a clinical embryologist in the particular clinic. Such persons would also be eligible to take a test to be designed and conducted by an appropriate designated authority, to qualify for a position of a clinical embryologist in a new clinic.) He / she must be familiar with the following:

- Principles and practice of semen analysis and cryopreservation of semen.
- Cytology of mammalian and human oocyte to identify stages of oocyte maturation accurately.
- All aspects of embryology including developmental biology.
- Cell biological techniques used in cell and tissue culture.
- Molecular biology and genetics of human reproduction.
- Micromanipulation of sperm and oocytes for carrying out ICSI and single-cell biopsies of embryos for preimplantation genetic diagnosis.
- Principles and functioning of all the equipment used in the laboratory.
- In vitro fertilization of oocytes after processing the gametes.
- Principles and practice of embryo freezing.

The responsibilities of the clinical embryologist would be:

- To ensure that all the necessary equipments are present in the laboratory and are functional.
- To perform all the procedures pertaining to processing, handling and culturing of gametes and embryos in the laboratory and hand over the embryo to the gynaecologist.
- To maintain records of all the procedures carried out in the laboratory.

In case of shortage of adequately trained clinical embryologists, an individual may act as a clinical embryologist for more than one clinic but each clinic where the person works must own responsibility for the embryologist and ensure that the embryologist is able to take care of the entire work load of the clinic without compromising on the quality of service. An embryologist must not be associated with more than two centers at any given time.

2.4 Counsellor

A person who has at least a degree (preferably a post-graduate degree) in Social Sciences, Psychology, Life Sciences or Medicine, and a good knowledge of the various causes of infertility and its social and gender implications, and the possibilities offered by the various treatment modalities, should be considered as qualified to occupy this position. The person should have a working knowledge of the psychological stress that would be experienced by potential patients, and should be able to counsel them to assuage their fears and anxiety and not to have unreasonable expectations from ART. A member of the staff of an ART clinic who is not engaged in any other full-time activity in the clinic can act as a counsellor.

The counsellor must invariably apprise the couple of the advantages of adoption as against resorting to ART involving a donor. An individual may act as a counsellor for more than one clinic but each clinic where the counsellor works must own responsibility for the counsellor and ensure that the counsellor is able to take care of the entire counselling load of the clinic without compromising on the quality of the counselling service.

2.5 Programme Co-ordinator / Director

This should be a senior person who has had considerable experience in all aspects of ART. The programme co-ordinator / director should be able to co-ordinate the activities of the rest of the team and ensure that staff and administrative matters, stock keeping, finance, maintenance of patient records, statutory requirements, and public relations are taken care of adequately. He / she should ensure that the staff are keeping up with the latest developments in their subject, by providing them with information from the literature, making available to them access to the latest journals, and encouraging them to participate in conferences and meetings and present their data. The programme co-ordinator / director should have a post-graduate degree in an appropriate medical or biological science. In addition, he / she must have a reasonable experience of ART.

PART – 3

3. Minimal Physical Requirements for an ART Clinic

A well designed ART clinic of Level 2 or Level 3 (Paras 1.3 and 1.4) should have a non-sterile and a strictly sterile area as detailed below. Some of the spaces mentioned below could be combined (that is, the same space may be used for more than one purpose) as long as such a step does not compromise the quality of service. However, the space provision for the sterile area cannot be combined with that for the non-sterile area and vice-versa. For Level 1B infertility care units (para 1.2), a strictly sterile area will not be required; the space requirement for such a clinic will, however, include a reception area, a waiting room for the patients, a consulting room for the gynaecologist, and requirements mentioned under para 3.9, 3.10 and 3.11.

3.1 The non-sterile area

The non-sterile area must include what is listed under paras 3.2 to 3.10.

3.2. A reception and waiting room for patients

3.3 An examination room with privacy

A separate examination room with privacy for interviewing and examining male and female partners independently is essential. Adequate measures must be taken to ensure that history taking and examination are carried out in strict privacy, maintaining the dignity of the patients. In case a male doctor examines a female patient, there must always be a female attendant present. The room must be equipped with an examination table and gynaecological instruments for examining the female per vaginum, and an appropriate ultrasonographic machine.

3.4 A general-purpose clinical laboratory

3.5 Store room

A well-stocked store for keeping essential stock of especially those items that have to be imported, precluding the need to be caught short in the middle of treatment, is required. Facilities must be available for storing sterile (media, needles, catheters, Petri dishes and such-like items) and non-sterile material under refrigerated and non-refrigerated conditions as appropriate.

3.6 Record room

Record keeping must be computerized so that data is accessible retrospectively for analysis or when called upon by the supervisory agency. The data must include essential details of the patient's

records, it must contain history of the cause of infertility as diagnosed earlier, results of new diagnosis if relevant, the treatment option best suited for the particular patient, the treatment carried out and the outcome of treatment, and follow-up if any. Any other noteworthy point such as possible adverse reaction to drugs, must be recorded. The software must have archival, retrieval and multivariate statistical analysis capabilities.

3.7 Autoclave room

A separate facility must be available for sterilizing and autoclaving all surgical items as well as some of those to be used in the in vitro culture laboratory.

3.8 Steps for vermin proofing

Adequate steps should be taken to make the whole clinic vermin proof, with suitable traps for preventing insects and other forms of unwanted creatures entering the clinic. This essential detail should be planned at an early stage because no pesticide can be used in a fully functional IVF clinic, as it could be toxic to the gametes and embryos.

3.9 Semen collection room

This must be a well-appointed room with privacy and an appropriate environment; it should be located in a secluded area close to the laboratory (see the next sub-section). Such a facility must be available in-house rather than having the patient collect the sample and bring it to the laboratory for analysis as, in the latter case, semen quality and identity is likely to be compromised. Procedures for collection of semen as described in the WHO Semen Analysis Manual must be followed with special reference to the type of container used; these containers must be sterile, maintained at body temperature and non-toxic. This room must have a washbasin with availability of soap and clean towels. The room must also have a toilet and must not be used for any other purpose.

3.10 Semen processing laboratory

There must be a separate room with a laminar air flow for semen processing, preferably close to the semen collection room. This laboratory must also have facilities for microscopic examination of post-coital test smears. Good Laboratory Practice (GLP) guidelines as defined internationally must be followed. Care must be taken for the safe disposal of biological waste and other materials (syringes, glass slides, etc.). Laboratory workers should be immunized against hepatitis B and tetanus.

3.11 Clean room for IUI

There must be a separate clean room with an appropriate table for IUI.

3.12 The sterile area

The sterile area shall house the operation theatre, a room for embryo transfer and an adjoining embryology laboratory. Entry to the sterile area must be strictly controlled by an anteroom for changing footwear, an area for changing into sterile garments and a scrub-station. The sterile area must be air-conditioned where fresh air filtered through an approved and appropriate filter system is circulated at ambient temperature (22-25⁰C).

3.13 The operation theatre

This must be well equipped with facilities for carrying out surgical endoscopy and transvaginal ovum pick-up. The operation theatre must be equipped for emergency resuscitative procedures.

3.14 Room for embryo transfer

This room must be in the sterile area and have an examination table on which the patient can be placed for carrying out the procedure and then rest undisturbed for a period of time. The operation theatre can be used for this purpose.

3.15 The embryology laboratory complex

The embryology laboratory must have facilities for control of temperature and humidity and must have filtered air with an appropriate number of air exchanges per hour. Walls and floors must be composed of materials that can be easily washed and disinfected; use of carpeting must be strictly avoided. The embryology laboratory must have the following:

- A laminar flow bench with a thermostatically controlled heating plate
- A stereo microscope
- A routine high-powered binocular light microscope
- A high-resolution inverted microscope with phase contrast or Hoffman optics, preferably with facilities for video recording
- A micromanipulator (if ICSI is done)
- A CO₂ incubator, preferably with a back up
- A hot air oven
- A laboratory centrifuge
- Equipment for freezing embryos in a programmed manner
- Liquid nitrogen cans
- A refrigerator

Appropriate steps need to be taken for the correct identification of gametes and embryos to avoid mix-ups. All material from the operation room, culture dishes and Falcon tubes for sperm collection (including lids), must bear the name of the patient. In the incubator, identified oocytes and sperm should be kept together on the same tray and double-checked. Pipettes used should be disposed off immediately after use. The embryology laboratory must have daily logbook in which all the day's activities are recorded, including the performance of the equipment.

3.16 Ancillary laboratory facilities

The infertility clinic need to have in-house facilities to perform all the procedures necessary to diagnose infertility, such as those mentioned in the two sub-section that follow. They can be out sourced to speciality laboratories delivering such services, as long as they are located in the neighborhood.

3.17 Hormone and other assays

The infertility clinic must have ready access to laboratories that are able to carry out immunoassays of hormones (FSH, LH, Prolactin, hCG, TSH, Insulin, Estradiol, Progesterone, Testosterone and DHEA) and tests such as for HIV and Hepatitis B. Endocrine evaluation constitutes an essential diagnostic procedure to determine the cause of infertility. It is also necessary to estimate blood estradiol in samples taken from a woman undergoing controlled ovarian hyperstimulation, and have the result on the same day to determine the dose of drugs to be given for induction of ovulation. Accurate monitoring of endocrine response to controlled ovarian stimulation goes a long way in preventing ovarian hyperstimulation.

3.18 Microbiology and histopathology

Another important facility in an ART clinic (or easily accessible to it) would be that of a microbiology laboratory that can carry out rapid tests for any infection, and a clinical chemistry laboratory. Facilities for carrying out hisopathological studies on specimens obtained from the operation theatre would also be desirable.

3.19 Maintenance of the laboratories

Each laboratory must maintain in writing, standard-operating manuals for the different procedures carried out in the laboratory. It should be ensured that there is no 'mix up' of gametes or embryos. The patient's name should be clearly labelled on all the tubes, dishes and pipettes containing the gametes and embryos. All pipettes should be immediately discarded after use.

Laminar flowhoods, laboratory tables, incubators and other areas where sterility is required must be periodically checked for microbial contamination using standard techniques, and a record of such checks must be kept.

A log book must be maintained which records the temperature, carbon dioxide content and humidity of the incubators and the manometer readings of the laminar air flow.

All instruments must be calibrated periodically (at least once every year) and a record of such calibration maintained.

3.20 Quality of consumables used in the laboratory

All disposable plasticware must be procured from reliable sources after ensuring that they are not toxic to the embryo. Culture media used for processing gametes or growing embryos in vitro should be preferably procured from reliable manufacturers. Each batch of culture medium needs to be tested for sterility, endotoxins, osmolality and pH. The embryologist should know the composition of the media that are being used. Most media are supplemented with serum; they should, therefore, be tested for antibodies to HIV 1 and 2, Hepatitis B Surface Antigen and Hepatitis C RNA.

3.21 Back-up power supply

A power back-up in the form of a UPS system and / or a captive power generative system must be available in infertility clinics of Level 1B, 2 or 3.

PART – 4

4. Assisted Reproductive Technology (ART) Procedures:

A variety of ART procedures have been described in the literature. The commonly used procedures that have been widely tested and proven to be satisfactory as of writing this document are listed below. One of the primary concerns of all ART treatments is the safety of the patients and of their gametes and embryos which constitute the very beginning of a new individual's life. The basic tenets of any medical treatment mentioned in the Helsinki Declaration of 1964 as received from time to time, clearly spell out the ethical concerns of treating patients. These basic tenets are also applicable to ART. The clinic must ensure that a particular ART being offered has been appropriately tested according to the norms of scientific practice, or – if experimental – has a sound scientific basis as adjudged by peers, and is fully in consonance with the diagnosis made of the cause of infertility. More particularly, the clinic must make sure that patients are well informed about

the treatment being offered to them, the reasons of suggesting a particular form of treatment, and alternative therapies available if any.

ART clinics in the country should bring to the notice of the National Advisory Board or a State Board on a continuing basis, any new procedure for the practice of which there would appear to be a sound scientific case. The National Advisory Board / State Board or a body appointed by it shall approve or disapprove the new procedure within six months of its having been made aware of in writing; if this is not done, the clinic could continue to use the procedure until the above body has taken a decision on it. No new procedure that has not been approved as above shall be permitted to be used by an infertility clinic for more than the period mentioned above. The National Advisory Board may, on its own initiative, approve a new assisted reproductive technology procedure.

4.1 Artificial insemination with husband's semen (AIH)

The technique consists of placing the husband's unprocessed semen inside the vagina.

4.2 Artificial insemination with donor semen (AID)

AID involves placing of donor's semen obtained from an accredited semen bank inside the vagina. The common indications for AID are when there is (a) non-obstructive azoospermia; (b) the husband has a hereditary genetic defect; (c) the couple has Rh incompatibility; or (d) the man has severe oligozoospermia and the couple does not wish to undergo any of the sophisticated ART such as ICSI.

4.3. Intrauterine insemination with either husband's or donor semen (IUI-H or IUI-D)

IUI involves the processing of semen in the laboratory so as to yield pure, active sperm, devoid of seminal plasma, which are then directly placed into the uterus.

Common indications for IUI are:

- Hostile uterine cervix.
- Oligozoospermia
- Unexplained infertility

4.4. In vitro fertilization and embryo transfer (IVF-ET)

The technique of IVF consists of bringing about the fertilization of the oocyte by the spermatozoa in the laboratory instead of in the woman's fallopian tube. IVF involves controlled ovarian stimulation to obtain multiple oocytes, followed by appropriate monitoring at the appropriate

moment of follicular growth, the follicles are aspirated to obtain the oocytes. The oocytes are mixed with appropriately capacitated spermatozoa from the husband (or the donor, if the medical condition indicates the use of donor sperm) and kept in an incubator for fertilization which is observed microscopically after 16 to 18 hours. Embryos are transferred into the uterine cavity between days 2 and 6 after oocyte aspiration. If implantation takes place, pregnancy can be confirmed 14 to 16 days after embryo transfer by determining the presence of hCG in a blood or urine sample. Such a test is reliable only when progesterone is used for luteal supplementation instead of hCG.

The original indication for IVF was irreversible pathology of the fallopian tubes, resulting from an inflammatory process or from previous surgery. However, in recent years the indications for IVF include infertility due to a subnormal male factor.

Some other indications are:

- Idiopathic infertility.
- Endometriosis.
- Infertility of immunological origin.

4.5 IVF associated techniques

Gamete Intrafallopian Tube Transfer (GIFT) or Tubal Embryo Transfer (TET) has been recommended for patients with healthy fallopian tubes. Access to the tube is gained by laparoscopy or by retrograde catheterization through the uterine cervix.

4.6 Intracytoplasmic sperm injection (ICSI) with ejaculated, epididymal or testicular spermatozoa

It is well known that the incidence of fertilization with sub-optimal semen is much lower in contrast to normal semen samples. It has been argued that since a sizeable number of couples are not suitable for IVF because of poor sperm parameters, alternate methods must be found to facilitate fertilization. Several approaches have been developed to circumvent the barriers (the zona pellucida and the ooplasmic membrane) that prevent the sperm reaching the ooplasm. Notable amongst these are: partial zona dissection (PZD), subzonal insemination (SUZI), and intracytoplasmic sperm injection (ICSI). Live birth have been reported using all these methods. The use of PZD or SUZI must be discouraged, as they do not offer any distinct advantage. ICSI is the most widely accepted choice of treatment for male factor infertility. ICSI can be carried out with fresh or frozen-thawed ejaculated or epididymal/testicular motile (live) spermatozoa.

4.6.1 Indications of ICSI with ejaculated spermatozoa

Examples are:

- Severe male-factor infertility.
- Fertilization failure after standard IVF treatment.
- Number of spermatozoa in the ejaculate too low for IVF.

4.6.2 Indications of ICSI with surgically retrieved sperm (MESA/PESA/TESA/TESE)

Microsurgical Epididymal Sperm Aspiration involves aspiration of sperm from epididymis under magnification, using microsurgical principles.

Percutaneous Epididymal Sperm Aspiration (PESA) and Testicular Sperm Aspiration / Extraction (TESA / TESE) are simplified, minimally invasive outpatient procedures that allow the physician to recover the sperm for fertilization in patients with obstructive azoospermia (lack of sperm in semen).

PESA requires a needle to be introduced percutaneously into the epididymis and the contents aspirated. The aspirate is observed under the microscope to determine if motile sperm are present.

In TESA, the needle is introduced in the testicle itself. In TESE, the semen-iferous tubules along with the sperm are introduced surgically.

Examples of indications are:

- Congenital bilateral absence of the vas deferens (CBAVD).
- Obstructive azoospermia
- Non-obstructive azoospermia
- Anejaculation.
- Retrograde ejaculation.

4.6.3 Indications of ICSI with in vitro matured oocytes

- Polycystic ovary
- History of ovarian hyperstimulation syndrome (OHSS)

4.7 Oocyte donation (OD) or embryo donation (ED)

Oocyte donation would involve fertilizing the oocyte(s) of an anonymous oocyte donor with the husband's sperm and transferring the resultant embryo into the infertile female partner. Embryo donation involves transferring of an embryo generated using anonymous oocyte and sperm donors into the female partner.

4.7.1 Indications for oocyte donation

Examples are:

- Gonadal dysgenesis.
- Premature ovarian failure.
- Iatrogenic ovarian failure due to ovarian surgery or radiation, or chemical castration.
- Women who have resistant ovary syndrome, or who are poor responders to ovulation induction.
- Women who are carriers of recessive autosomal disorders.
- Women who have attained menopause.

Donors should be healthy (as determined by medical and psychological examination, screening for STDs, and absence of HIV antibodies) women in the age group of 18-35 years. The recipient should be a healthy woman (determined by medical and psychological examination) having normal genitalia (as determined by physical examination) and uterine cavity (as determined by hystero-salpingography). In case of OD, the semen characteristics of the husband must be determined to see if they are in conformity with those associated with normal fertility. The blood group of the donor should be noted; the donor should also be tested for HIV, HBsAg, HCV and VDRL

4.7.2 Indications for embryo donation

This is generally resorted to whom the male partner of a couple requiring oocyte donation has indications such as:

- Primary germ cell failure
- Inheritable genetic disorder

4.8 Cryopreservation

Facilities for cryopreservation are an essential component of an ART Clinic and a semen bank as they are used under a variety of conditions such as those described below.

4.8.1 Freezing of semen

Men that are likely to suffer from psychological stress at the time of ovum pick-up or those who cannot be present at the time of ovum pick-up, are recommended to have their semen frozen for use at the appropriate time. One of the important reasons for freezing semen from donors is that any donor semen has to be quarantined for six months. The safety of using frozen sperm has been abundantly proven, both by experimental work and the actual results in humans. Matters of concern are the donor's

health and necessity to avoid donors who are infected of with venereal diseases, hepatitis B or C, or HIV. One of the drawbacks of sperm freezing is the likelihood of an approximately 20% loss in motility after thawing. Donors whose semen is frozen for future use are required to report to the semen bank six months after donation to be checked for HIV infection / disease status.

4.8.2 Freezing of embryos

Embryos are routinely cryopreserved to enable storage of supernumerary embryos, as up to a maximum of only three embryos is allowed for transfer at one time to avoid the risk of multiple pregnancies. Embryo freezing is a widespread routine procedure to increase cumulative pregnancy rates. Human embryos can be successfully cryopreserved at any stage from zygote to blastocyst, using 1, 2 propanediol (PROH) or dimethylsulfoxide (DMSO) for zygotes and cleaved embryos, and glycerol for blastocysts. The formation of ice crystals is of concern during embryo freezing. Using programmed, slow freezers reduces this problem considerably, and slow cooling is the most widely employed method. Human embryos are known to survive a simple ultra-rapid procedure of fast cooling but there is not much data on the efficacy of these techniques when used routinely. Straws or ampoules used for freezing embryos should be carefully and permanently labeled for identification purpose. Patients should be fully informed before the treatment cycle on the procedure of cryopreservation, the risks and, particularly, what is to be done with their embryos if they do not use them. They should sign a consent form concerning the agreement for embryo freezing as well as for the future use of the embryos. When a serum supplementation is used in the preparation of freezing and thawing solutions, one must carefully avoid any risk of viral transmission to the embryo through the serum.

4.8.3 Oocyte cryopreservation

This procedure has the potential of creating oocyte banks. The oocyte can be thawed at a later date, and used by the patient herself or for oocyte donation. However, the success rates in terms of fertilization, pregnancy and live births with the use of cryopreserved oocytes have yet to be firmed up. Much remains to be learnt on identifying the optimal stage of oocyte development when cryopreservation would be of value.

4.8.4 Ovarian tissue cryopreservation

Although this technique is yet in its infancy, it has the potential for young women with conditions such as malignancy or severe endometriosis.

4.9 In vitro culture media

There has been a spurt of new media introduced for in vitro culture of gametes and embryos. If one takes a close look at these media, they are products that have evolved over the years. However, some manufacturers do not give the exact composition of their media but merely state that for reasons of patent protection or as trade secret they are constrained to give full details of the composition of their media (J D Biggers, Reproductive Biomedicine Online, Vol.1, No.3, 2000; also available on the world-wide web; rbmonline.com). This is an undesirable situation. Infertility clinics that deal with human embryos and the future life of the products they create in the laboratory must be privy to the knowledge about the media they use, if need be by signing an appropriate confidentiality agreement which would prohibit the clinic from using or passing on the proprietary information provided by the manufacturers of the media to any other organization that may commercially exploit this information. When a serum supplementation has to be used in the preparation of media, one must carefully avoid the risk of viral transmission to the embryo through the serum.

PART – 5

5. Patient Selection

Patient selection for referral and, finally, for ART should be based on the findings of basic investigations on the cause of infertility. These investigations should include the following:

5.1 Husband

- Physical examination, both systemic and local, to detect any problem that might be the cause of infertility or that may modify the management of infertility.
- Detailed semen analysis; if any abnormality is detected, repeat tests should be done after suitable intervals. An abnormal finding on a repeat semen examination warrants full-scale investigation by an appropriate specialist to ascertain the cause and then institute the necessary treatment.
- Screening for infections including syphilis, HBV, HCV and HIV and their appropriate management.
- If needed, appropriate endocrinological investigations and therapy.

5.2 Wife

- Physical examination, both systemic and local, to detect any problem that might be the cause of infertility or that may modify the management of infertility.
- Detection and timing of ovulation by appropriate tests, for example, cervical mucus studies, ultrasonography, premenstrual endometrial biopsy, histopathological examination, and serum progesterone estimation in the midluteal phase.
- Assessment of tubal patency by appropriate investigations such as hystero-salpingography, sonosalpingography, or laparoscopy if required, to find out / rule out specific problems and to select the appropriate therapy.
- Screening for local factors including cervical mucus-related problems and lower genital tract infections, and instituting appropriate therapy.
- Assessment of uterine cavity by hysteroscopy if needed.
- Screening for HBV, HCV and HIV, and for other reproductive tract infections such as syphilis, Chlamydia, and tuberculosis if necessary.
- If needed, appropriate endocrinological investigations and therapy.

Any gynaecologist not specifically trained in the subspeciality of infertility care can also complete these investigations. Based on the results of these investigations, couples should be selected for treatment at different levels of infertility care units (described in Part-1).

5.3 Patient selection for treatment in different infertility care units

In general, infertile couples can be categorized broadly into three groups; (1) those with single defect in one of the partners; (2) those with multiple defects in one or both the partners; (3) no apparent defect in either partner (unexplained infertility).

5.4 Single defect in one of the partner

The fault may exist either in the male or in the female partner. The defect may be either treatable or untreatable. For example, in the female partner, a treatable defect could be tough or imperforate hymen, or oligo or anovulation due to polycystic ovary syndrome or a sub-mucous fibroid. The untreatable female partner defects would

include premature ovarian failure, absence of uterus, dense pelvic adhesions due to endometriosis, tuberculosis, and pelvic inflammatory disease as a sequel to pelvic surgery. Unlike female factor infertility, male factor infertility is seldom easily correctable. If a single defect in one of the partners is correctable, some of the patients will respond to conventional medical or surgical therapy while the others will not. Further treatment for the unresponsive couples will then consist of counselling and an in-depth investigation, leading to the use of ART – failing which, adoption may be the only alternative. For an uncorrectable single defect, either in the male or in the female partner, the choice would be between ART and adoption. The alternative to be chosen should be suggested by the counsellor after evaluation of the age, financial capabilities and psychological attitude of the couple.

5.5 Multiple defects in one or both partners

When multiple defects involve either one or both partners, attempt to correct these defects and hoping to achieve a pregnancy in the natural way is many-a-time unsuccessful. This should be explained by the consulting gynaecologist / physician to the couple to prevent unnecessary expenditure by the couple. Judicious and effective counselling plays a very vital role under such circumstances; at least some couples will accept that at this point their treatment (such as surgical) ends. Some of them will then opt for adoption while others might wish to try the challenges of ART procedures.

PART – 6

6. Selection criteria for ART

The choice of the procedure used, e.g. IVF-ET, GIFT, ZIFT, or ICSI, is made depending upon the needs, resources and circumstances of the couple, availability of the facilities, and experience and expertise of the gynaecologist / embryologist.

6.1 Tubal disease

IVF-ET can be offered where microsurgical techniques for tubal and peritoneal disease have failed or are unlikely to benefit the patient. The presence of peritubal adhesions, condition of the tubal wall, condition of the ciliary epithelium and degree of fimbrial damage would dictate the choice between IVF and microsurgery. Patients who have already undergone tuboplasty and those with inaccessible ovaries would be more suitable for IVF. In case of history of ectopic pregnancy, IVF would be a better option.

6.2 Endometriosis

IVF is a suitable option for (a) women with moderate to severe endometriosis; (b) those in whom medical or surgical therapy has failed; and (c) sometimes in cases of mild to moderate endometriosis in the presence of other factors contributing to infertility.

6.3 Unexplained infertility

Couples who have prolonged unexplained infertility could benefit from IVF, as many factors such as subtle ovulation defects, defects in ovum pick-up, gamete transport, tubal environment, sperm abnormality, or oocyte abnormality, may come to light when IVF is used.

6.4 Immunological factor

IVF can be used when there are antisperm antibodies either in the male or the female and when other techniques such as immunosuppression, use of condoms, intrauterine insemination and other therapeutic measures have failed.

6.5 Cervical factor

IVF may be offered for cervical factor only if repeated attempts (6 to 8 cycles) of intrauterine insemination have failed and other therapies have not resulted in pregnancy.

6.6 Male factor

IVF-ET is the logical therapy in cases of low concentrations of sperm (say less than 10 million/ml), low motility (less than 30%), and / or abnormal sperm morphology (presence of >60% abnormal forms). No universally accepted minimal sperm concentration for success in IVF exists. In cases of severe male factor infertility, assisted fertilization by means of micromanipulation and sperm injection (ICSI) can be offered even in obstructive and non-obstructive cases. In severe oligozoospermia, teratozoospermia, cryptozoospermia and azospermia (obstructive / non-obstructive), ICSI can be employed using either ejaculated or epididymal sperm.

6.7 Ovarian disorders

IVF-ET can benefit patients with hypogonadotropic anovulation, oligoovulation and luteal phase deficiency, although IVF is rarely indicated when these disorders exist as isolated conditions. IVF-ET can be used for women with luteinized unruptured follicle syndrome in polycystic ovarian disease.

6.8 Uterine disorders

Patients with Mullerian agenesis or congenital uterine anomalies, women with severe intrauterine adhesion refractory to surgical lysis of the adhesion, and hysterectomized patients can, through IVF, transfer their embryos to a surrogate mother.

6.9 Use of donor oocytes and donor embryos

Women who have undergone premature or timely menopause and women in the perimenopausal age group who do not show proper recruitment of follicles and who have other existing causes of infertility, can avail of the option of donor oocytes and donor embryos. Women with genetic disorders, those who have undergone radiation therapy, and those with ovaries that are not accessible by ultrasound due to severe adhesions, can also be advised to avail of donor oocytes for IVF-ET.

6.10 Selection criteria for gamete intra-fallopian transfer (GIFT)

The indications for GIFT are almost similar to that for IVF-ET, except that GIFT cannot be performed on those who have both the fallopian tubes blocked.

6.11 Choosing between IVF-ET and GIFT

Decision in regard to which of these techniques should be utilized, must be individualized for each patient. The advantages of IVF over GIFT are documentation of fertilization, less trauma and relatively lower anaesthetic risk. There is no exposure to excess quantities of carbon dioxide in IVF as happens during laparoscopic insufflation with GIFT. On the other hand, GIFT is more natural as fertilization occurs in the tubal ampulla, the gametes are minimally exposed in vitro, and early embryo development occurs in a natural environment.

6.12 Micro-manipulation of gametes and embryos (SUZI and ICSI), AH and embryo biopsy

Subzonal insemination (SUZI), intracytoplasmic sperm injection (ICSI) and assisted hatching (AH) need micromanipulation of gametes. SUZI involves sperm injection in vitro, into the subzonal space of oocytes. This technique has now been virtually totally replaced by ICSI, which involves injection of sperm into the cytoplasm of the oocyte and which is useful in a variety of cases such as aging ova, elderly women, repeated failure of implantation in IVF, and in certain cases of male factor infertility. Assisted hatching of embryo by drilling a hole in the zona pellucida is resorted prior to embryo transfer for improving implantation rates. Embryo biopsy is a procedure in which one or more blastomeres are removed from the embryo for PGS (Preimplantation Genetic Screening) to improve implantation rates, or for PGD

(Preimplantation Genetic Diagnosis) to rule out genetic disorders; it must not be used for sex determination / selection unless medically indicated.

6.13 Complications

ART procedures carry a small risk both to the mother and the offspring. These risks must be explained to the couple and appropriate counselling done. ART procedures are to be initiated only after patients understand these risks and still want to undergo ART. Some of the most commonly encountered risks are mentioned in the following four sub-sections (this list is not exhaustive).

6.13.1 Multiple gestation

Specific efforts must be made to reduce the incidence of multiple pregnancies. Therefore, not more than three oocytes should be transferred for GIFT and not more than three embryos for IVF-ET at one sitting, excepting under exceptional circumstances (such as elderly women, poor implantation, advanced endometriosis or poor embryo quality) which should be recorded; the remaining embryos, if any, may be cryopreserved and, if required, transferred at a later cycle.

6.13.2 Ectopic pregnancy

Ectopic pregnancy rates could be as high as 5% for ART procedures. The choice of an appropriate procedure as per guidelines given earlier, especially in persons with tubal disease, may reduce the chances of an ectopic pregnancy.

6.13.3 Spontaneous abortion

Abortion rates rise with increasing age of the mother and in multiple pregnancies, especially with three or more fetuses. In cases where more than two fetuses are present, selective embryo reduction may be advised. It is essential that the advantages of foetal reduction (better chances of the survival of the other fetuses and the fact that they are likely to be born nearer term and with better birth weight) and disadvantages (the possibility that there might be an increased risk of abortion following the procedure) must be explained to the couple, and their informed consent taken before embryo reduction is attempted.

6.13.4 Ovarian hyperstimulation syndrome

The use of superovulation for ART entails a risk of hyperstimulation in some women, in the range of 0.2 to 8.0%. The extent of this risk is determined by the number of follicles

and eggs, the estradiol values (greater than 2500 pg/ml), the dose used for triggering ovulation, the ability to aspirate all the follicles at the time of oocyte retrieval, and several other factors. The programme director should be fully aware of the means to avoid hyperstimulation and also its treatment. Careful monitoring and management will reduce this risk as well as the morbidity associated with it.

PART – 7

7 Information and counselling to be given to patients

Information must be given to couples seeking treatment, on the points given in the following paragraphs:

- The basis, limitations and possible outcome of the treatment proposed, variations in its effectiveness over time, including the success rates with the recommended treatments obtained in the clinic as well as around the world (this data should be available as a document with references, and updated every 6-12 months).
- The possible side-effects (e.g. of the drug used) and the risks of treatment to the women and the resulting child, including (where relevant) the risks associated with multiple pregnancy.
- The need to reduce the number of viable foetuses, in order to ensure the survival of at most two foetuses.
- Possible disruption of the patient's domestic life which the treatment may entail.
- The techniques involved, including (where relevant) the possible deterioration of gametes or embryos associated with storage, and possible pain and discomfort.
- The cost (with suitable break-up) to the patient of the treatment proposed and of an alternative treatment, if any (there must be no other 'hidden costs').
- The importance of informing the clinic of the result of the pregnancy in a pre-paid envelope.
- The need to make the couple aware, if relevant, that a child born through ART has a right to seek information about his genetic parent / surrogate mother on reaching 18 years, excepting information on the name and address – that is, the individual's personal identity – of the gamete donor or the surrogate mother. The couple is not obliged to

provide the information to which the child has a right, on their own to the child when he / she reaches the age of 18, but no attempt must be made by the couple to hide this information from the child should an occasion arise when this issue becomes important for the child.

- The advantages and disadvantage of continuing treatment after a certain number of attempts.

Pamphlets (one-page on each technique in all local languages and English) which give clear, precise and honest information about the procedure recommended to be used will help the couple make an informed choice.

FORM - A
(See Rules 10.1 and 14.1)

**FORM OF APPLICATION FOR REGISTRATION OR RENEWAL OF
REGISTRATION OF AN INFERTILITY / ART CLINIC**

(To be submitted in duplicate with supporting documents as enclosures, also in duplicate)

[Attach separate sheets where necessary]

1. Full name and address / addresses of ART Clinic with telephone/telegraphic address / telex / fax / e-mail
2. Name of the person to whom correspondence should be addressed (specify Shri / Smt. / Kum. / Dr.)
3. Address of the above person
4. Designation of the above person [specify owner / partner / managing director / other (to be stated)]
5. Type of facility to be registered (specify Primary (Level 1B) / Secondary (Level 2) / Tertiary (Level 3) ART Clinic)
6. Type of ownership and organization (specify individual ownership/partnership / company / co-operative / any other). In case of type of organization other than individual ownership, furnish copy of articles of association and names and addresses of other persons responsible for management, as enclosures
7. Type of institution (Govt. Hospital / Municipal Hospital / Public Hospital / Private Hospital / Private Nursing Home / Private Clinic / Private Laboratory / any other to be stated)
8. ART procedures for which facilities exist
9. Space available for the ART Clinic (give total work area excluding lobbies, waiting rooms, stairs etc; enclose floor plan)
10. Instruments and equipment available, with the make and model of each equipment (list on a separate sheet)
11. Laboratory tests for which facilities are available at the ART Clinic:
 - (a)
 - (b)
 - (c)
 -

12. Staff members, with qualifications, experience and duties of each (list on a separate sheet)

13. For renewal application only:

- (a) Registration No.
- (b) Date of issue and date of expiry of the existing Certificate of Registration

14. List of enclosures:

Please attach a list of enclosures giving the supporting documents submitted with this application.

(.....)
Name and signature of applicant

Date :
Place :

DECLARATION

I, Shri / Smt./ Kum. / Dr., son / daughter / wife of, aged years, resident of
....., hereby declare that I have read and understood the Assisted Reproductive Technology (Regulation) Act, 2008, and the Assisted Reproductive Technology (Regulation) Rules, 2008.

2. I also undertake to explain the said Act and Rules to all employees of the ART Clinic in respect of which registration is sought, and ensure that the Act and the Rules are fully complied with.

(.....)
Name and signature of applicant

Date:
Place:

[Strike out whichever is not applicable or not necessary. All enclosures are to be authenticated by signature of the applicant.]

ACKNOWLEDGEMENT

(See Rule 10.2]

The application in Form A in duplicate for grant* / renewal* of registration ART Clinic by (name and address of applicant) has been received by the Appropriate Authority on (date).

The list of enclosures attached to the application in Form A has been verified with the enclosures submitted and found to be correct.

*OR

On verification it is found that the following documents mentioned in the list of enclosures are not actually enclosed.

This acknowledgement does not confer any rights on the applicant for grant or renewal of registration.

(.....)
Signature and designation of
Registration Authority, or
authorized person in the
Office of the Registration Authority.

Date: SEAL

ORIGINAL
DUPLICATE FOR DISPLAY

*Strike out whichever is not applicable or necessary.

FORM – A (1)
(See Rules 10.1 and 14.1)

**FORM OF APPLICATION FOR REGISTRATION OR RENEWAL OF
REGISTRATION OF A SEMEN BANK**

(To be submitted in duplicate with supporting documents as enclosures, also in duplicate)

[Attach separate sheets where necessary]

1. Full name and address / addresses of the Semen Bank with telephone / telegraphic address / telex / fax / e-mail
2. Name of the person to whom correspondence should be addressed (specify Shri / Smt. / Kum. / Dr.)
3. Address of the above person
4. Designation of the above person [specify owner / partner / managing director / other (to be stated)]
5. Type of ownership and organization (specify individual ownership /partnership /company / co-operative / any other). In case of type of organization other than individual ownership, furnish copy of articles of association and names and addresses of other persons responsible for management, as enclosures
6. Type of institution (Govt. / Private / any other to be stated)
7. Space available (give total work area excluding stairs etc; attach floor plan)
8. Instruments and equipment available, with the make and model of each equipment (list on a separate sheet)
9. Laboratory tests for which facilities are available at the Semen Bank:
 - (a)
 - (b)
 - (c)
 -
10. Staff members, with qualifications, experience and duties of each (list on a separate sheet)
11. For renewal application only:
 - (a) Registration No.
 - (b) Date of issue and date of expiry of the existing Certificate of Registration

12. List of enclosures:

Please attach a list of enclosures giving the supporting documents submitted with this application.

(.....)
Name and signature of applicant

Date :
Place :

DECLARATION

I, Shri / Smt./ Kum. / Dr. , son / daughter / wife of, aged years, resident of

....., hereby declare that I have read and understood the Assisted Reproductive Technology (Regulation) Act, 2008, and the Assisted Reproductive Technology (Regulation) Rules, 2008, and that the Semen Bank on behalf of which I am making this application operates independently of – and is not a part of – any ART clinic.

2. I also undertake to explain the said Act and Rules to all employees of the ART Clinic in respect of which registration is sought, and ensure that the Act and the Rules are fully complied with.

(.....)
Name and signature of applicant

Date:
Place:

[Strike out whichever is not applicable or not necessary. All enclosures are to be authenticated by signature of the applicant.]

ACKNOWLEDGEMENT

(See Rule 10.2]

The application in Form A in duplicate for grant* / renewal* of registration of
..... (Semen Bank) by
(name and address of applicant) has been received by the Appropriate Authority
..... on (date).

The list of enclosures attached to the application in Form A has been verified with
the enclosures submitted and found to be correct.

*OR

On verification it is found that the following documents mentioned in the list of
enclosures are not actually enclosed.

This acknowledgement does not confer any rights on the applicant for grant or
renewal of registration.

(.....)
Signature and designation of
Registration Authority, or
authorized person in the
Office of the Registration Authority.

Date: SEAL

ORIGINAL
DUPLICATE FOR DISPLAY

*Strike out whichever is not applicable or necessary.

FORM – A (2)
(See Rules 10.1 and 14.1)

**FORM OF APPLICATION FOR REGISTRATION OR RENEWAL OF
REGISTRATION OF A RESEARCH CENTRE USING HUMAN EMBRYOS**

(To be submitted in duplicate with supporting documents as enclosures, also in duplicate)

[Attach separate sheets where necessary]

1. Full name and address / addresses of the Research Centre with telephone / telegraphic address / telex / fax / e-mail
2. Name of the person to whom correspondence should be addressed (specify Shri / Smt. / Kum. / Dr.)
3. Address of the above person
4. Designation of the above person
5. Type of institution (Govt. / Private)
6. If Private, is the institution recognized as a research centre by the Dept. of Scientific and Industrial Research, Government of India ?
7. Total floor area of the Research Centre
8. Major Instruments and equipments available, with the make and model of each equipment (list on a separate sheet)
9. Members of the top administrative body / research advisory committee
10. Top 20 members of the scientific staff with qualifications and experience
11. Does the Research Centre publish an annual report ? If so, please attach a copy of the last report.
12. For renewal application only:
 - (a) Registration No.
 - (b) Date of issue and date of expiry of the existing Certificate of Registration

13. List of enclosures:

Please attach a list of enclosures giving the supporting documents submitted with this application.

Date: _____
Place: _____
Name and signature of applicant

DECLARATION

I, Shri / Smt./ Kum. / Dr. , son / daughter / wife of, aged years, resident of

....., hereby declare that I have read and understood the Assisted Reproductive Technology (Regulation) Act, 2008, and the Assisted Reproductive Technology (Regulation) Rules, 2008, and that the Semen Bank on behalf of which I am making this application operates independently of – and is not a part of – any ART clinic.

2. I also undertake to explain the said Act and Rules to all employees of the Research Centre in respect of which registration is sought, and ensure that the Act and the Rules are fully complied with.

(.....)
Name and signature of applicant

Date:
Place:

[Strike out whichever is not applicable or not necessary. All enclosures are to be authenticated by signature of the applicant.]

ACKNOWLEDGEMENT

(See Rule 10.2]

The application in Form A in duplicate for grant* / renewal* of registration of
..... (Research Centre) by
(name and address of applicant) has been received by the Appropriate Authority
..... on (date).

The list of enclosures attached to the application in Form A has been verified with
the enclosures submitted and found to be correct.

*OR

On verification it is found that the following documents mentioned in the list of
enclosures are not actually enclosed.

This acknowledgement does not confer any rights on the applicant for grant or
renewal of registration.

(.....)
Signature and designation of
Registration Authority, or
authorized person in the
Office of the Registration Authority.

Date: SEAL

ORIGINAL
DUPLICATE FOR DISPLAY

*Strike out whichever is not applicable or necessary.

FORM - B
(See Rule 12.1)

CERTIFICATE OF REGISTRATION
(To be issued in duplicate)

1. In exercise of the powers conferred under Section 11(6) of the Assisted Reproductive Technology (Regulation) Act, 2008, the Appropriate Authority hereby grants registration to the ART Clinic of Level 1B / Level 2 / Level 3* named below for purposes of carrying out Assisted Reproductive Technology Procedures as per the aforesaid Act, for a period of three years ending on

A. Name and address of the ART Clinic

B. Name of applicant for registration

2. This registration is granted subject to the aforesaid Act and Rules thereunder and any contravention thereof shall result in suspension or cancellation of this certificate of registration before the expiry of the said period of three years.

3. Registration No. allotted

4. For renewed Certificate of Registration only:

Period of validity of earlier Certificate of Registration from to

Signature, name and designation of
the Registration Authority

Date:

SEAL

DISPLAY ONE COPY OF THIS CERTIFICATE AT A CONSPICUOUS PLACE AT
THE PLACE OF BUSINESS

*Strike out whichever is not applicable or necessary.

FORM - C
(See Rule 12.2)

**REJECTION OF APPLICATION FOR REGISTRATION OR
RENEWAL OF REGISTRATION**

In exercise of powers conferred under Section 11(6) of the Assisted Reproductive Technology (Regulation) Act 2008, the Appropriate Authority hereby rejects the application for grant* / renewal* of registration of the ART Clinic named below for the reasons stated.

Name and address of the ART Clinic :

Name of applicant who has applied for registration :

Reasons for rejection of application for registration :

Signature, name and designation
of the Registration Authority

Date:

SEAL

*strike out whichever is not applicable or necessary

FORM - D

Consent Form to be signed by the Couple for IVF and ICSI

(See Rule 15.1)

We have requested the Centre (named above) to provide us with treatment services to help us bear a child.

We understand and accept (as applicable) that:

1. The drugs that are used to stimulate the ovaries to raise oocytes have temporary side effects like nausea, headaches and abdominal bloating. Only in a small proportion of cases, a condition called ovarian hyperstimulation occurs where there is an exaggerated ovarian response. Such cases can be identified ahead of time but only to a limited extent. Further, at times the ovarian response is poor or absent in spite of using a high dose of drugs. Under these circumstances, the treatment cycle will be cancelled.
2. There is no guarantee that:
 - a. The oocytes will be retrieved in all cases.
 - b. The oocytes will be fertilized.
 - c. Even if there were fertilization, the resulting embryos would be of suitable quality to be transferred.

All these unforeseen situations will result in the cancellation of any treatment.

3. There is no certainty that a pregnancy will result from these procedures even in cases where good quality embryos are transferred.
4. Medical and scientific staff can give no assurance that any pregnancy will result in the delivery of a normal living child.
5. **Endorsement by the ART Clinic**

I/we have personally explained to _____
and _____ the details and implications of his / her / their signing this consent / approval form, and made sure to the extent humanly possible that he / she / they understand these details and implications.

6. This consent would hold good for all the cycles performed at the clinic.

Name and signature of the Male Partner

Name and signature of the Female Partner

Name, address and signature
of the Witness from the clinic

Name and signature of the Doctor

Name and address of the ART clinic

Dated:

FORM - E

Consent for Artificial Insemination or Intrauterine Insemination with Husband's Semen / Sperm

(See Rule 15.1)

_____ and _____
_____, being husband and wife and both of legal age,
authorize Dr. _____ to inseminate the wife artificially or
intrauterine with the semen / sperm of the husband for achieving conception.

We understand that even though the insemination may be repeated as often as recommended by the doctor, there is no guarantee or assurance that pregnancy or a live birth will result.

We have also been told that the outcome of pregnancy may not be the same as those of the general pregnant population, for example in respect of abortion, multiple pregnancies, anomalies or complications of pregnancy or delivery.

The procedure carried out does not ensure a positive result, nor does it guarantee a mentally and physically normal child. This consent holds good for all the cycles performed at the clinic.

Endorsement by the ART Clinic

I / we have personally explained to _____ and _____
the details and implications of his / her / their signing this consent / approval form,
and made sure to the extent humanly possible that he / she / they understand these
details and implications.

Name, address and signature of the Witness from the clinic

Signed: _____ (Husband)

_____(Wife)

Name and signature of the Doctor

Name and address of the ART clinic

Dated:

FORM - F

Consent for Artificial Insemination or Intrauterine Insemination with Donor Semen

(See Rule 15.1)

We, _____ and _____, being husband and wife and both of legal age, authorize Dr. _____ to inseminate the wife artificially or intrauterine with semen / sperm of a donor (semen bank's no. _____; obtained from _____ semen bank with valid registration no.....) for achieving conception.

We understand that even though the insemination may be repeated as often as recommended by the doctor, there is no guarantee or assurance that pregnancy or a live birth will result.

We have also been told that the outcome of pregnancy may not be the same as those of the general pregnant population, for example in respect of abortion, multiple pregnancies, anomalies or complications of pregnancy or delivery.

We declare that we shall not attempt to find out the identity of the donor.

I, the husband, also declare that should my wife bear any child or children as a result of such insemination(s), such child or children shall be as my own and shall be my legal heir(s).

The procedure carried out does not ensure a positive result, nor does it guarantee a mentally and physically normal body. This consent holds good for all the cycles performed at the clinic.

Endorsement by the ART Clinic

I / we have personally explained to _____ and _____ the details and implications of his / her / their signing this consent / approval form, and made sure to the extent humanly possible that he / she / they understand these details and implications.

Name, address and signature
of the Witness from the clinic

Signed : _____(Husband)

_____(Wife)

Name and signature of the Doctor

Name and address of the ART clinic

Dated:

FORM - G
Consent for Freezing of Embryos
(See Rule 15.1)

We, _____ and _____, consent to freezing of the embryos that have resulted out of IVF/ICSI with our gametes. We understand that the embryos would be normally kept frozen for five years. If we wish to extend this period, we would let you (the ART Clinic) know at least six months ahead of time. If you do not hear from us before that time, you will be free to (a) use the embryos for a third party; (b) use them for research purposes; or (c) dispose them off. We also understand that some of the embryos may not survive the subsequent thaw and that frozen embryo-replaced cycles have a lower pregnancy rate than when fresh embryos are transferred.

***Husband / man**

In the unforeseen event of my death, I would like

The embryos to perish

To be donated to my wife / partner

To be donated to a third party

Used for research purposes

Signed:

Dated:

***Wife / woman**

In the unforeseen event of my death, I would like

The embryos to perish

To be donated to my husband / partner

To be donated to a third party

Used for research purposes

Signed:

Dated:

Endorsement by the ART Clinic

I / we have personally explained to _____ and _____ the details and implications of his / her / their signing this consent / approval form, and made sure to the extent humanly possible that he / she / they understand these details and implications.

Name, address and signature of the Witness from the clinic

Name and signature of the Doctor

Dated

Name and address of the ART clinic

*The appropriate option may be ticked

FORM - H

Consent for the Procedure of PESA and TESA

(See Rule 15.1)

Name of female partner

Name of male partner

We hereby request and give consent to the procedure of PESA and TESA for ICSI, to be performed on the male partner.

We understand that

- a) There is no guarantee that the sperm will be successfully removed or that sperm will necessarily fertilise our oocytes.
 - b) Should the sperm retrieval fail, the following options will be available for the retrieved oocytes.
 - i) Insemination of all or some oocytes using donor sperm
 - ii) Donation of oocytes to another infertile couple
 - iii) Disposal of oocytes according to the ethical guidelines
- (Tick the appropriate option)

Each of the above points has been explained to us by

The procedure(s) carried out does (do) not ensure a positive result, nor do they guarantee a mentally and physically normal body. This consent holds good for all the cycles performed at the clinic.

Endorsement by ART Clinic

I/we have personally explained to _____ and _____ the details and implications of his / her / their signing this consent / approval form, and made sure to the extent humanly possible that he / she / they understand these details and implications.

Signature of Male Partner

Name, address and
signature of the Witness
from the clinic

Signature of Female Partner

Name and signature of the Doctor

Name and address of the ART clinic

Dated

FORM - I
Consent for Oocyte Retrieval / Embryo Transfer
(See Rule 15.1)

Woman's name:

Woman's address:

Name and address of the Clinic:

I have asked the Clinic named above to provide me with treatment services to help me bear a child. I consent to:

- a) Being prepared for oocyte retrieval by the administration of hormones and other drugs
- b) The removal of oocytes from my ovaries under ultrasound guidance / laparoscopy
- c) The mixing of the following (using technologies such as IVF or ICSI):

<input type="checkbox"/>	My oocytes	<input type="checkbox"/>	the sperm of my husband
<input type="checkbox"/>	Anonymous donor oocyte	<input type="checkbox"/>	anonymous donor sperm

- d) the placing in my _____ of
- e) 1. _____ (no) of the oocytes mixed with the sperm
- f) 2. _____ (no) of the resulting embryos
- g) 3. _____ (no) of our cryo-preserved embryos
- h) 4. _____ (no) of embryo(s) obtained anonymously

(Tick the appropriate and strike off the others)

I had a full discussion with _____ about the above procedures and I have been given oral and written information about them.

I consent that I shall be the legal mother of the child and the child will have all the legal rights on me, in case of anonymous gamete / embryo donation.

I have been given a suitable opportunity to take part in counselling about the implications of the proposed treatment.

The type of anaesthetic proposed (general / regional / sedation) has been discussed in terms which I have understood.

Endorsement by the ART Clinic

I/we have personally explained to _____ and _____ the details and implications of her signing this consent / approval form, and made sure to the extent humanly possible that she understands these details and implications.

Signature of Female Partner

Name, address and signature
of the Witness from the clinic

Name and signature of the Doctor

Consent of Husband

As the husband, I consent to the course of the treatment outlined above. I understand that I will become the legal father of any resulting child, and that the child will have all the normal legal rights on me.

Name, address and signature: _____
(Husband)

Name, address and signature
of the Witness from the clinic: _____

Name and signature of the Doctor: _____

Dated

FORM - J
Agreement for Surrogacy
(See Rule 15.1)

I, _____ (the woman), with the consent of my husband (name), of _____ (address) have agreed to act as a host mother for _____ who are / is unable (or do not wish to) have a child by any other means.

I had a full discussion with _____ of the clinic on _____ in regard to the matter of my acting as a surrogate mother for the child of the above couple.

I understand that the methods of treatment may include:

1. Stimulation of the genetic mother for follicular recruitment
2. The recovery of one or more oocytes from the genetic mother by ultrasound guided oocyte recovery or by laparoscopy.
3. The fertilization of the oocytes from the genetic mother with the sperm of her husband or an anonymous donor.
4. The fertilization of a donor oocyte by the sperm of the husband.
5. The maintenance and storage by cryopreservation of the embryo resulting from such fertilization until, in the view of the medical and scientific staff, it is ready for transfer.
6. Implantation of the embryo obtained through any of the above possibilities into my uterus, after the necessary treatment if any.

I have been assured that the genetic mother and the genetic father have been screened for HIV and hepatitis B and C before oocyte recovery and found to be seronegative for all these diseases. I have, however, been also informed that there

is a small risk of the mother or / and the father becoming seropositive for HIV during the window period.

I consent to the above procedures and the administration of such drugs that may be necessary to assist in preparing my uterus for embryos transfer, and for support in the luteal phase.

I understand and accept that there is no certainty that a pregnancy will result from these procedures.

I understand and accept that the medical and scientific staff can give no assurance that any pregnancy will result in the delivery of a normal and living child.

I am unrelated / related (relation) _____
to the couple (the would-be genetic parents).

I have worked out the financial terms and conditions of the surrogacy with the couple in writing and an appropriately authenticated copy of the agreement has been filed with the clinic, which the clinic will keep confidential.

I agree to hand over the child to _____, or _____
and _____ in case of a couple, or to _____
in case of their separation during my pregnancy, or to the survivor in case of the death of one of them during pregnancy, as soon as I am permitted to do so by the hospital / clinic / nursing home where the child is delivered.

I undertake to inform the ART Clinic, _____, of the result of the pregnancy.

I take no responsibility that the child delivered by me will be normal in all respects. I understand that the biological parent(s) of the child has / have a legal obligation to accept the child that I deliver and that the child would have all the inheritance rights of a child of the biological parent(s) as per the prevailing law.

I will not be asked to go through sex determination tests for the child during the pregnancy and that I have the full right to refuse such tests. I will, however, agree to foetal reduction if asked by the party seeking surrogacy, in case I happen to be carrying more than one foetus.

I understand that I would have the right to terminate the pregnancy at my will; I will then refund all certified and documented expenses incurred on the pregnancy by the biological parents or their representative. If, however, the pregnancy has to be terminated on expert medical advice, these expenses will not be refunded.

I have been tested for HIV, hepatitis B and C and shown to be seronegative for these viruses just before embryo transfer.

I certify that (a) I have not had any drug intravenously administered into me through a shared syringe; (b) I have not undergone blood transfusion; and (c) I and my husband have had no extramarital relationship in the last six months.

I also declare that I will not use drugs intravenously, undergo blood transfusion excepting of blood obtained through a certified blood bank, and avoid sexual intercourse during the pregnancy.

I undertake not to disclose the identify of the party seeking the surrogacy.

In the case of the death or unavailability of any of the party seeking my help as the surrogate mother, I will deliver the child to _____
or _____ in this order; I will be provided, before the embryo transfer into me, a written agreement of the above persons that they will be legally bound to accept the child in the case of the above-mentioned eventuality.
(If applicable) My husband has approved my acting as a surrogate.
(Strike off if not applicable.)

Endorsement by the ART Clinic

I/we have personally explained to _____ and _____ the details and implications of his / her / their signing this consent / approval form, and made sure to the extent humanly possible that he / she / they understand these details and implications.

Signed:

(Surrogate Mother)

Name, address and signature
of the Witness from the clinic

Name and signature of the Doctor

Name and address of the ART clinic

Dated

FORM - K
Consent Form for the Donor of Eggs
(See Rule 15.1)

I, Ms. _____ consent to donate my eggs to couples who are unable to have a child by other means.

I have had a full discussion with Dr. _____
(name and address of the clinician) on _____

I have been counselled by _____
(name and address of independent counsellor) on _____

I understand that there will be no direct or indirect contact between me and the recipient, and my personal identity will not be disclosed to the recipient or to the child born through the use of my gamete.

I understand that I shall have no rights whatsoever on the resulting offspring and vice versa.

I understand that the method of treatment may include:

- Stimulating my ovaries for multifollicular development.
- The recovery of one or more of my eggs under ultrasound-guidance or by laparoscopy under sedation or general anesthesia.
- The fertilization of my oocytes with recipient's husband's or donor sperm and transferring the resulting embryo into the recipient.

(If applicable) My husband has agreed to the donation of my oocyte. (Strike off if not applicable.)

Endorsement by the ART Clinic

I / we have personally explained to _____ the details and implications of her signing this consent / approval form, and made sure to the extent humanly possible that she understands these details and implications.

Signed: _____

Name, address and signature of the Witness from the clinic

Name and signature of the Doctor

Name and address of the ART clinic

Dated

FORM - L
Consent Form for the Donor of Sperm
(See Rule 15.1)

I, Mr. _____ consent to donate my sperm to couples who are unable to have a child by other means.

I have had a full discussion with Dr. _____
(name and address of the clinician) on _____,

I have been counselled by _____
(name and address of independent counsellor) on _____

I understand that there will be no direct or indirect contact between the recipient, and me, and my personal identity will not be disclosed to the recipient or to the child born through the use of my gamete.

I understand that I shall have no rights whatsoever on the resulting offspring and vice versa.

(If applicable) My wife has agreed to the donation of my sperm. (Strike off if not applicable.)

Endorsement by the semen bank

I / we have personally explained to _____ the details and implications of his signing this consent / approval form, and made sure to the extent humanly possible that he understands these details and implications.

Signed: _____

Name and signature of the Doctor

Name, address and signature
of the Witness from the Semen Bank

Name and address of the Semen Bank

Dated

FORM - M
Information on Semen Donor
(See Rule 15.1)

Date of filling the form:

BASIC INFORMATION:

1. Identification number (Donor ID)
2. Age / Date of birth
3. Marital status
4. Education :
 - a. Donor
 - b. Spouse
5. Occupation :
 - a. Donor
 - b. Spouse
6. Monthly income
7. Religion

HISTORY:

8. Obstetric history of wife :
 - a. Number of deliveries
 - b. Number of abortions
 - c. Other points of note
9. History of use of contraceptives

10. Medical history

11. Family history from the medical point of view

12. History of any abnormality in a child of the donor

13. History of blood transfusion

14. History of substance abuse

INVESTIGATIONS:

15. Blood group and Rh status

16. Complete blood picture:

a. Hb

b. Total RBC count

c. Total WBC count

d. Differential WBC count

e. Platelet count

f. Peripheral smear

17. Random blood sugar

18. Blood urea / Serum creatinine

19. SGPT

20. Routine urine examination

21. HBsAg status

22. Hepatitis C status

23. HIV ⁽¹⁾ status with date of the tests done

24. Hemoglobin A2 (for thalassemia) status

25. HIV PCR ⁽²⁾ (positive or negative)

26. Any other specific test ⁽³⁾

FEATURES:

27. Height

28. Weight

29. Colour of skin

30. Colour of hair

31. Colour of eyes

DETAILED PHYSICAL EXAMINATION:

- 32. Pulse
 - 33. Blood pressure
 - 34. Temperature
 - 35. Respiratory system
 - 36. Cardiovascular system
 - 37. Per abdominal examination
 - 38. Other systems
-

Footnotes:

- (1) To be carried out every 6 months
 - (2) To be carried out if donor leaves within 6 months of the previous HIV test
 - (3) Any additional test carried out on the basis of the history and examination of donor
-

All the tests should have been done within 15 days prior to the date of filling the form.

Name and signature with date, of the person filling the form:

FORM – M (1)

Information on Egg Donor
(See Rule 15.1)

Date of filling the form (except items 16-26)

Date of filling items 16-26

BASIC INFORMATION:

1. Identification number (Donor ID)
2. Age / Date of birth
3. Marital status
4. Education :
 - a. Donor
 - b. Spouse
5. Occupation :
 - a. Donor
 - b. Spouse
6. Monthly income
7. Religion

HISTORY:

8. Obstetric history
 - a. Number of deliveries
 - b. Number of abortions
 - c. Other points of note
9. Menstrual history
10. History of use of contraceptives
11. Medical history

12. Family history from the medical point of view

13. History of any abnormality in a child of the donor

14. History of blood transfusion

15. History of substance abuse

INVESTIGATIONS⁽¹⁾:

16. Blood group and Rh status
17. Complete blood picture:
 - a. Hb
 - b. Total RBC count
 - c. Total WBC count
 - d. Differential WBC count
 - e. Platelet count
 - f. Peripheral smear
18. Random blood sugar
19. Blood urea / Serum creatinine
20. SGPT
21. Routine urine examination
22. HBsAg status
23. Hepatitis C status
24. HIV status with date of the tests done

25. Hemoglobin A2 (for thalassemia) status
26. Any other specific test ⁽²⁾

FEATURES:

27. Height
28. Weight
29. Colour of skin
30. Colour of hair
31. Colour of eyes

DETAILED PHYSICAL EXAMINATION:

32. Pulse
33. Blood pressure
34. Temperature
35. Respiratory system
36. Cardiovascular system
37. Per abdominal examination

Other systems

Footnotes:

- (1) To be carried out within 15 days prior to oocyte donation
 - (2) Any additional test carried out on the basis of the history and examination of donor
-

To the patient, a copy of this form without items 16-26 filled in, may be given when asked for. The investigations in items 16-26 may be done when the patient has chosen the donor provisionally, subject to the results of tests in items 16-26 being satisfactory.

Name(s) and signature(s) with date, of persons filling the form:

FORM – M (2)

Information on Surrogate
(See Rule 15.1)

Date of filling the form (except items 20-31)

Date of filling items 20-31

BASIC INFORMATION:

1. Identification number
2. Name
3. Age / Date of birth
4. Address
5. Photograph
6. Tel no.
7. Marital status
8. Education :
 - a. Surrogate
 - b. Spouse
9. Occupation :
 - a. Surrogate
 - b. Spouse
10. Monthly Income
11. Religion

HISTORY:

12. Obstetric history :
 - a. Number of deliveries
 - b. Number of abortions
 - c. Other points of note

13. Menstrual history
14. History of use of contraceptives
15. Medical history

16. Family history

17. Has she acted as surrogate earlier : Yes No

If so, how many times did it lead to a successful pregnancy?

18. History of blood transfusion

19. History of substance abuse

INVESTIGATIONS⁽¹⁾:

20. Blood group and Rh status
21. Complete blood picture
 - a. Hb
 - b. Total RBC count
 - c. Total WBC count
 - d. Differential WBC count
 - e. Platelet count
 - f. Peripheral smear
22. Random blood sugar

23. Blood urea / Serum creatinine
24. SGPT
25. Routine urine examination
26. HBsAg status
27. Hepatitis C status
28. HIV status
29. Hemoglobin A2 (for thalassemia) status
30. HIV PCR ⁽¹⁾ :
 - a. Surrogate
 - b. Spouse
31. Any other specific test⁽²⁾

FEATURES:

32. Height
33. Weight
34. Colour of skin
35. Colour of hair
36. Colour of eyes

DETAILED PHYSICAL EXAMINATION:

37. Pulse
38. Blood pressure
39. Temperature
40. Respiratory system
41. Cardiovascular system
42. Per abdominal examination
43. Per speculum examination

- 44. Per vaginal examination
 - 45. Trans-vaginal sonography
 - 46. Other systems
-

Footnotes

- (1) To be carried out within 15 days prior to embryo transfer. Test no.30 to be done only if Test 28 is negative.
 - (2) Any additional test carried out on the basis of the history and examination of the surrogate OR any test requested by the recipient who shall pay for the additional requested test
-

To the patient, a copy of this form without items 20-31 filled in, may be provided when asked for. The investigations in items 20-31 may be done when the patient has chosen the surrogate provisionally, subject to the results of tests in items 20-31 being satisfactory.

Name(s) and signature(s) with date(s) of person(s) filling the form:

FORM - N

Results of screening of Semen Donors / Oocyte Donors / Surrogate Mothers
(See Rule 15.1)

(To include every individual screened)

Identification number	Screened for [★]	Date(s)	2 nd date after six months for semen donors	Suitable (Yes/No)	Name ⁺	Signature ⁺

-
- ★ A: Semen donation
 - B: Oocyte donation
 - C: Surrogate mother

+ Name and signature of the person certifying suitability or otherwise

FORM - O

Record of use of Donor Gametes and Surrogates

(See Rule 15.1)

(A separate form to be used for each individual donor or surrogate)

Name of Semen Bank :

Registration no.

A. For Donor Semen

Donor ID	Sample ID	Collection date	Name of person signing	Signature	Supply date	ART Clinic	Registration no.	Receipt attached

FORM - O
B. For Oocyte Donors

Donor ID	Recruitment date	Name of person signing	Signature	Supply date	ART Clinic	Receipt attached (Yes / No)

FORM - O

C. For Surrogate mother

Surrogate ID	Recruitment date	Name of person signing	Signature	Supply date	ART Clinic	Patient(s) Name(s) / ID

The Semen Bank will maintain a separate register which will give the name and address, telephone no. etc., of the donor / surrogate that will match with the donor / surrogate ID mentioned above. This register will be kept in a safe, under lock and key, and will be accessible to only a small number of persons in the Semen Bank who will be sworn on oath in Form V to maintain the above identity secret.

Form - P
Oocyte-Embryo Record
(See Rule 15.1)

Patient name:

ID no.:

Day 0 Date: Time: Sci.: Dr.:		Day 1 Date: Sci: Diss. Time: Score Time: Hrs.(from OPU):			Day 2 Date: Sci.: Time: Hrs.:			Day 3 Date: Sci.: Time: Hrs.:		Day 4 Date: Sci.: Time: Hrs.:	Day 5 Date: Sci.: Time: Hrs.:		Frozen Info. Date: Time: Method: Slow / Vitri	
Hyal. Time: Inject Time:					Sci: Sci:									
Egg	Comm.	PN	PB	Comm.	Cell#	Grade	Frag %	Cell#	Grade			FATE	Cell#/ Grade	Straw no.
1														
2														
3														
4														
5														
6														
7														
8														
9														
10														
11														
12														
13														
14														
15														

Frozen embryo details :
Tank :
Canister :
Goblet/Loop :
Arrangement :

**Form - P (1)
Details of the Frozen Embryos**

Patient name :

ID No. :

Freeze date :

1st thaw :

Date :

Time :

Thaw medium :

Straw#	Cell stage / grade at freezing	Post-thaw cell stage / grade	Fate
S			
S			
S			
S			
S			

Embryos transferred :

Sci.:

Comments :

Date :

Time :

Dr. :

Embryos remaining :

ASSISTED HATCHING : YES/NO

Date:

Time:

Sci:

2nd thaw :

Date :

Time :

Thaw medium:

Straw#	Cell stage / grade at freezing	Post-thaw cell stage / grade	Fate
S			
S			
S			
S			
S			

Embryos transferred :

Sci.:

Comments :

Date :

Time :

Dr. :

Embryos remaining :

ASSISTED HATCHING : YES/NO

Date:

Time:

Sci.:

Date of freezing:

Scheduled date of discard:

Frozen embryos: Discarded / Used for

Date:

Sci.:

Explanation of non-standard abbreviations:

Sci. = Scientist; Diss.= Dissection; OPU = Ovum pick-up;

Hyal = Hyalase; Info. = Information; Vitri. = Vitrification;

PB = Polar bodies; PN = Pronuclei; Comm. = Comments; Frag = Fragmentation

Form - Q Semen Analysis Report

(See Rule 15.1)

Semen Bank Registration no.:

Donor ID no.:

Doctor	Date & Time	Abstinence (Days)	Produced at
			<input type="checkbox"/> Centre <input type="checkbox"/> Home

Purpose: IUI ANALYSIS FREEZING TRIAL WASH

Basic semen analysis				
	Pre wash	Post wash	Acceptable (WHO) values	
Volume (ml)			2.0-5.0	
Sperm count (mill/ml)			≥ 20	
Motility (%)			≥ 50	
Activity (%)	(Rapid)	(Moderate)	(Slow)	(Sluggish)
Viscosity	<input type="checkbox"/> 0	<input type="checkbox"/> 1+	<input type="checkbox"/> 2+	<input type="checkbox"/> 3+
Agglutination	<input type="checkbox"/> 0	<input type="checkbox"/> 1+	<input type="checkbox"/> 2+	<input type="checkbox"/> 3+
Debris	<input type="checkbox"/> 0	<input type="checkbox"/> 1+	<input type="checkbox"/> 2+	<input type="checkbox"/> 3+
Normal Morphology (%)				
Morphological abnormalities: (%)				
Head	Mid-Piece		Tail	
Amorphous		Cytoplasmic droplet		Coiled tail
Elongated		Others		Short tail
Pyriform				Hairpin tail
Macrocephalic				Double tail
Microcephalic				OTHERS
Broken neck				
Double head				
Others				
Hypo-osmotic Swelling Test : %				
Semen Frozen : <input type="checkbox"/> Yes <input type="checkbox"/> No		No. of Vials Frozen :		Location :

<p>Remark : Acceptable / Not acceptable</p>	<p>Biologist: Name:</p> <p>Signature:</p>
----------------------------------------------------	--------------------------------------------------------------------

If unacceptable, receipt of remaining semen sample returned to the donor along with a copy of this report, should be attached.

FORM - R

Contract between the Semen Bank and the Semen Donor

(See Rule 15.1)

The Semen Bank and the Donor agree to come into this contract today on the _____ day of _____ month, 2008, in _____ as per the following conditions.

First Part being _____ Semen bank, having its office at _____, and the registered office at _____, herein referred to as the Bank (which expression shall, unless repugnant to the context or meaning thereof, be deemed to mean and include legal representatives, administrators, etc., of the said Bank);

And

Second Part being Mr. / Ms. _____ aged _____ residing at _____,

herein referred to as the Donor (which expression shall, unless repugnant to the context or meaning thereof, be deemed to mean and include legal representatives, administrators, etc., of the said Clinic)

Whereas

1. The first part is a semen bank that is established, amongst other purposes, to collect and store human semen for use in ART procedures.
2. The second part is an individual who has willingly agreed to donate his semen to the Bank against a consideration for the same.
3. That the Bank and the Donor have therefore, come to form this contract to facilitate the process with the laid down terms and conditions.

NOW THIS INDENTURE WITNESSETH THAT:

1. The Bank agrees to accept the semen of the Donor and to preserve it as per the rules laid down in the ART (Regulation) Act.
2. The Donor agrees to disclose the true facts of himself and not to suppress any personal details to the Bank, including family history, genetic background, criminal background, religion, etc. The Bank agrees to keep all information about the Donor confidential. No information shall be declared by the Bank except by an order of a court or to the Indian Council of Medical Research. If any information is suppressed by the Donor and that suppression causes any damage in the ART procedure or to the patient, then the Bank will not be responsible for it but only the Donor will be responsible and punishable under the provisions of law.
3. The Donor agrees to relinquish all parental rights over the child, which may be conceived from his gamete.
4. The donor, if married, agrees to take consent of his wife before donating his semen and also produce the same before the bank at the time of signing this agreement.
5. The bank agrees to inform the Donor about all the tests that would be necessary for the safety and protection of the ART procedure. The Donor agrees to undergo all the tests required by the Bank. The Bank also agrees to inform the Donor about the results of the above tests.
6. The Donor agrees to return to the Bank six months after the donation, to be screened for HIV positivity, if the semen is initially found to be of acceptable quality.
7. If the semen is not of acceptable quality, the Donor agrees that his semen that was collected and analysed would be returned to him and no payment would be due to him from the Bank.

8. The Bank agrees to pay the Donor a sum of Rs. _____ for each donation of his semen, if the semen is found to be of acceptable quality. Fifty per cent of the above sum shall be paid to the Donor by the Bank immediately after the donation; the remaining fifty per cent shall be paid to him on his testing negative for HIV after 6 months.

9. The Donor agrees to accept the above amount and thereafter make no other demands for the donation of semen by him.

10. The Bank and the Donor agree to abide by all the relevant provisions of Chapters V and VII, relating to “sourcing, storage, handling and record keeping for gametes, embryos and surrogate”, and rights and duties of patients, donors, surrogates and children”, respectively, of the ART (Regulation) Act.

11. This agreement is signed by both the parties after a clear understanding of all the issues involved, and in full senses and under no pressure from any person.

First Part

Second Part

Witness 1

Witness 2

Name, address and telephone number of the witnesses:

FORM – R (1)

Contract between the Semen Bank and the Oocyte Donor
(See Rule 15.1)

The Semen Bank and the Donor agree to come into this contract today on the _____ day of _____ month, 2008, in _____ as per the following conditions.

First Part being _____ semen bank, having its office at _____, and the registered office at _____, herein referred to as the Bank (which expression shall, unless repugnant to the context or meaning thereof, be deemed to mean and include legal representatives, administrators, etc., of the said Bank);

And

Second Part being Ms. _____ aged _____ residing at _____, herein referred to as the Donor (which expression shall, unless repugnant to the context or meaning thereof, be deemed to mean and include legal representatives, administrators, etc., of the said Clinic)

Whereas

1. The first part is semen bank that is established, amongst other purposes, to collect, screen and supply oocyte donor to ART clinics for use in ART procedures.
2. The second part is an individual who has willingly agreed to donate her oocytes to the ART clinic against a consideration for the same.
3. That the Bank and the Donor have, therefore, come to form this contract to facilitate the process with the laid down terms and conditions.

NOW THIS INDENTURE WITNESSETH THAT:

1. The Bank agrees to screen and select oocyte donors and to supply them to ART clinics desiring of oocyte donors as per the rules laid down in the ART (Regulation) Act.
2. The donor agrees to disclose the true facts of himself and not to suppress any personal details to the Bank, including family history, genetic background, criminal background, religion, etc. The Bank agrees to keep all information about the Donor confidential. No information shall be declared by the Bank except by an order of a court or to the Indian Council of Medical Research. If any information is suppressed by the Donor and that suppression causes any damage in the ART procedure or to the patient, then the Bank will not be responsible for it but only the Donor will be responsible and punishable under the provisions of law.
3. The Donor agrees to relinquish all parental rights over the child, which may be conceived from her gamete.
4. The donor, if married, agrees to take consent of her husband before donating her oocytes and also produce the same before the bank at the time of signing this agreement.
5. The bank agrees to inform the Donor about all the tests that would be necessary for the safety and protection of the ART procedure. The Donor agrees to undergo all the tests required by the Bank. The Bank also agrees to inform the Donor about the results of the above tests.
6. The Donor agrees to be assigned to any ART clinic as directed by the Bank for the purposes of undergoing oocyte donation.
7. The Donor agrees to undergo ovarian stimulation by taking regular medication as directed by the ART clinic and come regularly for follow up as directed.
8. The Donor agrees not to discontinue treatment midway except on medical advice of the ART clinic.

9. The Bank agrees to pay the Donor a sum of Rs. _____ for each oocyte donation procedure. Ten per cent of the above sum shall be paid to the Donor by the Bank on initiation of stimulation by the ART clinic; the remaining ninety per cent shall be paid to her after oocyte donation.
10. The Donor agrees to accept the above amount and thereafter makes no other demands for the donation of oocyte by her.
11. The Bank and the Donor agree to abide by all the relevant provisions of Chapters V and VII, relating to “sourcing, storage, handling and record keeping for gametes, embryos and surrogate”, and rights and duties of patients, donors, surrogates and children”, respectively, of the ART (Regulation) Act.
12. This agreement is signed by both the parties after a clear understanding of all the issues involved, and in full senses and under no pressure from any person.

First Part

Second Part

Witness 1

Witness 2

Name, address and telephone number of the witnesses:

FORM - R (2)

Contract between the Semen Bank and the Surrogate

(See Rule 15.1)

The Semen Bank and the Surrogate Mother agree to come into this contract today on the _____ day of _____ month, 2008, in _____ as per the following conditions.

First Part being the _____ semen bank, having its office at _____, and the registered office at _____, herein referred to as the Bank (which expression shall, unless repugnant to the context or meaning thereof, be deemed to mean and include legal representatives, administrators, etc., of the said Bank);

And

Second Part being Ms. _____, aged _____, residing at _____

_____ hereinafter referred to as the Surrogate (which expression shall, unless repugnant to the context or meaning thereof, be deemed to mean and include legal representatives, administrators, etc., of the said Clinic)

Whereas

1. The first part is a semen bank that is established, amongst other purposes, to screen and identify sperm / egg donors and surrogates, and store gametes.
2. The second part is an individual who has willingly agreed to be a surrogate mother against a consideration from the individual(s) [to be herein after called parent(s)] identified by the Bank.
3. That the Bank and the Surrogate have therefore come to form this contract to facilitate the process with the laid down terms and conditions.

NOW THIS INDENTURE WITNESSETH THAT:

1. The Bank agrees to treat the second part as the surrogate mother for the parent(s), _____ and _____. The Surrogate agrees to be a surrogate mother for the child of the above parent(s) identified by the Bank.
2. The Bank agrees to carry out on the Surrogate the needful precautionary tests required before the process of ART and the Surrogate agrees to undergo these tests, like for HIV and hepatitis B and C. Bank shall provide to the surrogate reliable documentary evidence that the genetic parents have undergone the necessary tests like for HIV, hepatitis B and C and that the results are negative.
3. The Bank has explained the process of treatment to be undergone by the Surrogate and the Surrogate has understood the treatment accordingly and has, after such understanding, agreed to the surrogacy.
4. The Surrogate agrees to bear the child for the pregnancy period and then handover the child born, to the parent(s). The surrogate clearly understands that the consideration for the surrogacy is to be paid by the parent(s) and the Bank will not be responsible for any demand by the surrogate in the form of compensation. The Bank shall also not be responsible for payment to the surrogate for any other expenses incurred during the surrogacy period.
5. The Surrogate assures the Bank that she will not undergo any sex determination test for the child during pregnancy.
6. The surrogate shall be under the observation of the ART Clinic chosen by the patient(s) during the period of the surrogacy. However, if any complications arise during the period, the ART Clinic / Bank shall not be responsible for them under any circumstances.

7. The Bank shall maintain all secrecy regarding the surrogacy and agrees not to disclose any information in this regard to anyone without the consent of the surrogate.
8. The Surrogate agrees to enter into an agreement with the parent(s), and to file an authenticated copy of the agreement with the Bank as well as with the ART Clinic.
9. The Surrogate agrees not to undergo embryo transfer for the parent(s) unless the Bank gives her a green signal to do so.
10. The surrogate agrees to inform the Bank about the result of the pregnancy.
11. Both the Surrogate and the Bank agree to abide by all the relevant provisions of Chapters V and VII on “sourcing, storage, handling and record keeping for gametes, embryos and surrogate”, and “rights and duties of patients, donors, surrogates and children”, respectively, of the ART (Regulation) Act, and Rule 15.2 (Form J) of the Rules and Regulations of the above Act.
12. Both the parties have entered into this agreement without any pressure on either side and in their full senses.

First Part

Second Part

Witness 1

Witness 2

Name, address and telephone number of the witnesses:

FORM - S

Contract between the Semen Bank and the Patient
(See Rule 15.1)

The semen Bank and the Patient agree to come into this contract today on the _____ day of _____ month, 2008, in _____ as per the following conditions.

First Part being _____ semen bank, having its office at _____, and the registered office at _____, hereinafter referred to as the Bank (which expression shall, unless repugnant to the context or meaning thereof, be deemed to mean and include legal representatives, administrators, etc. of the said Bank);

And

Second Part being Shri / Kum. / Smt. _____ aged _____, residing at _____, and Shri / Kum. / Smt. _____ aged _____, residing at _____ ★, herein referred to as the Patient (which expression shall, unless repugnant to the context or meaning thereof, be deemed to mean and include legal representatives, administrators, etc., of the said Patient).

Whereas

1. The first part is a semen bank that is established to screen and identify sperm / oocyte donors and surrogates and to store gametes.
2. The second part is an individual / couple who has approached the Bank for availing the services of a sperm / oocyte donor or as surrogate. ★

3. That the Bank and the Patient have, therefore, come to form this contract to facilitate the process with the laid down terms and conditions.

NOW THIS INDENTURE WITNESSETH THAT:

1. The Bank agrees to supply the semen / oocyte donor / surrogate★ selected by the patient to the ART clinic (registration no. _____) selected by the patient as per the rules laid down in the ART (Regulation) Act.
2. The Bank agrees to disclose to the Patient all the information it has and is required to have as per the rules laid down in the ART (Regulation) Act, about the sperm / oocyte donor or surrogate* (except the identity including name and address and any information that would allow the identity to be revealed, of the gamete donor). However, if any such information, or lack of any other information causes any damage to the ART procedure or to the patient, then the Bank will not be responsible for it.
3. The Bank agrees to inform the Patient about the result of all the tests carried out on the donor at the initiative of the Bank.
4. The patient agrees to pay the Bank a sum of Rs. _____ for the provision of each semen sample / oocyte donor / surrogate mother selected by the patient. *
5. The Bank agrees to accept the above amount and thereafter make no other demands for the provision of donor sperm / oocyte donor / surrogate mother*.
6. The patient agrees not to make any attempt to find out the identity of the sperm or oocyte donor.
7. The Bank and the Patient agree to abide by all the relevant provisions of Chapters V and VII, relating to “sourcing, storage, handling and record keeping for gametes, embryos and surrogate”, and “rights and duties of

patients, donors, surrogates and children”, respectively, of the ART (Regulation) Act.

8. This agreement is signed by both the parties after a clear understanding of all the issues involved, and in full senses and under no pressure from any person.

First Part

Second part

Witness 1

Witness 2

Name, address and telephone number of the witnesses:

FORM - T

Contract between the Semen Bank and the ART Clinic

(See Rule 15.1)

The Semen Bank and the ART Clinic agree to come into this contract today on the _____ day of _____ month, 2008, in _____ as per the following conditions.

First Part being _____ semen bank, having its office at _____, and the registered office at _____, herein referred to as the Bank (which expression shall unless repugnant to the context or meaning thereof, be deemed to mean and include legal representatives, administrators, etc., of the said Bank);

And

Second Part being _____ ART clinic having its clinic at _____, and the registered office at _____, herein referred to as the Clinic (which expression shall, unless repugnant to the context or meaning thereof, be deemed to mean and include legal representatives, administrators, etc., of the said Clinic)

Whereas

1. The first part is a semen bank that is established to screen and identify sperm / egg donors and surrogates and to store gametes.
2. The second part is a clinic working on infertility using various methods of ART (Assisted Reproductive Technologies).

3. The Bank would identify and / or preserve the things mentioned in para 1 and the clinic would use them to carry out the ART procedures.
4. The Bank and the Clinic have, therefore, come to form this contract to facilitate the use of ART by the needy people with the laid down terms and conditions.

NOW THIS INDENTURE WITNESSETH THAT:

1. The Bank agrees to do its best to provide the Clinic the kind of items mentioned above (semen, oocytes/oocyte donors, and surrogates) as and when required and in as many number as necessary.
2. The Clinic agrees to give the proper consideration for the use of the items taken from the Bank as per the rates mutually decided between the parties from time to time, and put on record.
3. The Bank shall ensure that the sperm / egg donor is free from HIV and hepatitis B and C, infections, hypertension, diabetes, sexually transmitted diseases, and identifiable and common genetic disorders such as thalassemia.
4. The Bank shall have an analysis carried out on the semen of the individual, preferably using a semen analyzer, and only the semen certified to be normal according to WHO's specification shall be provided to the ART Clinic
5. The blood group and the Rh status of the individual shall be determined and placed on record by the Bank.
6. Other relevant information in respect of the donor such as height, weight, age, educational qualifications, profession, colour of the skin and the eyes, record of major diseases including any psychiatric disorder, the family background in respect of history of any familial disorder, criminal record, and religion, shall be recorded by the Bank in an appropriate proforma.

7. On request for semen by the clinic, the Bank shall provide the Clinic with a list of donors (without the name or the address but with a code number) giving all relevant details as mentioned above.
8. The Clinic shall inform the bank about a successful clinical pregnancy and any successful birth that the Clinic comes to know of.
9. The Clinic shall use any item obtained from the Bank only for the specific purpose for which it was obtained.
10. The Bank or the Clinic shall not be responsible for the false report of any appropriately accredited laboratory for any specific tests.
11. The Clinic and the Bank shall ensure that all the provisions of Chapters IV, V and VII pertaining to the “duties of an ART clinic”, “sourcing, storage, handling and record keeping for gametes, embryos and surrogates”, and “rights and duties of patients, donors, surrogates and children”, respectively, are followed.
12. In case of any dispute between the Bank and the Clinic, the arbitrator appointed by the parties jointly shall resolve the dispute.

First Part

Second Part

Witness (1)

Witness (2)

Name, address and telephone number of the witnesses:

FORM - U

Contract between the Patient and the Surrogate

(See Rule 15.1)

The patient and the Surrogate mother agree to come into the contract today on the _____ day of _____ month, 2008, in _____ as per the following conditions.

First Part being the party [individual / couple, that may or may not be the genetic parent(s) of the child to be born] seeking surrogacy, herein referred to as the patient, Mr _____, aged _____, residing at _____

and / or Ms _____, aged _____, residing at _____

_____ (which expression shall, unless repugnant to the context or meaning thereof, be deemed to mean and include legal representatives, administrators, etc., of the said party);

And

Second Part being Ms. _____, aged _____, residing at _____

_____ herein referred to as the surrogate (which expression shall, unless repugnant to the context or meaning thereof, be deemed to mean and include legal representatives, administrators, etc., of the surrogate).

Whereas

1. The first part is the person(s) desiring surrogacy.

2. The second part is an individual who has willingly agreed to be the surrogate mother for a child of the patient, against a consideration from the patient for whom she has agreed to be the surrogate mother.
3. The patient and the surrogate have, therefore, come to form this contract to facilitate the process with the laid down terms and conditions.

NOW THIS INDENTURE WITNESSETH THAT:

1. The patient has agreed to have the surrogate deliver a child for the patient and the surrogate has agreed to do so after taking necessary consent from her (the surrogate's) husband.
2. The patient and the surrogate have agreed to abide by all the provisions as applicable, of Sections 34 and 36 and Rule 15.1 (Form J) of the ART (Regulation) Act.
3. As per the provision of Section 34.3 of the above-mentioned Act, the patient has agreed to pay in all Rs..... to the surrogate for delivering a child for the patient, in addition to the other expenses as per Section 34.2 of the above-mentioned Act. The surrogate agrees to accept the above amount for bearing a child for the patient. The payment of the above amount shall be made as follows:

1st instalment which will not be less than 75% of the total amount, of Rs..... at the time of embryo transfer.

2nd instalment of Rs..... at months after the embryo transfer, if the pregnancy is established.

3rd instalment of Rs..... at the time of handing over the child to the patient in the presence of two witnesses.

The above charges are for the first embryo transfer for the patient. If that does not succeed, for each subsequent embryo transfer within six months of

the first embryo transfer, the surrogate will receive (in addition to the payment already made) 50% of the total price agreed to initially, to be paid as follows:

25% (of the total price) at the time of embryo transfer.

...% at months after the embryo transfer, if the pregnancy is established.

...% at the time of handing over the child as above.

4. If the patient is not a citizen of India, or is a citizen of India but not normally resident in the city of residence of the surrogate, the following shall be the point of contact for the surrogate:

Name:

Complete address:

Telephone: Office..... Residence....., Cell.....

Fax:.....

E-mail.....

5. In the case of the death or unavailability of the patient, I shall deliver the child to the following in the given order:

(1) Name:

Address:

Telephone: Office.....Residence:.....Cell:.....

Fax::

E-mail:

(2) Name:

Address:

Telephone: Office.....Residence:.....Cell:.....

Fax::

E-mail:

The written consent of the above is attached. The above persons shall be legally bound to accept the child in case of the death or unavailability of the patient, when I am ready to deliver the child as per medical advise. They shall keep me informed of any change in address till I deliver the child to the patient or any one of the above.

5. The patient and the surrogate have willingly come to sign this agreement in full senses and without any pressure from any person.

First Part

Second Part

Witness (1)

Witness (2)

Name, address and telephone number of the witnesses:

Form - V

Oath of Secrecy

(See rule 15.1)

I,, Chairman/Member of, or a member of the staff of ART clinic/semen bank, with registration no.....*, hereby declare on oath that I shall not disclose any information pertaining to a patient (seeker of gamete donation, or of a surrogate mother) or to a gamete donor or surrogate mother, to which I may have access, to anyone at any time, without the permission of the patient, donor or the surrogate mother, as appropriate, except when asked by a Court of Law to do so. I understand that I will be liable to prosecution if I violate the above declaration.

Date: Signature
Place: (Name)

Address:
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Signature of witness 1

Signature of witness 2

(Names, addresses, and telephone numbers of the witnesses)

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