### **Sperm Donation & ART Banks Do's and Don'ts**



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# **Definition of Sperm bank**

 A sperm bank, semen bank or cryobank is a facility that collects and stores human <u>sperm</u> from <u>sperm donors</u> for use by women who need donorprovided sperm to achieve pregnancy. Sperm donated by the sperm donor is known as donor sperm, and the process for introducing the sperm into the woman is called <u>artificial insemination</u>, which is a form of <u>third party</u> <u>reproduction</u>.

#### According to Indian council of Medical Research

#### **Definitions** —

- "ART Bank", means an organisation that is set up to supply sperm, oocytes / oocyte donors and surrogate mothers to Assisted reproductive technology clinics or their patients;
- "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;
- "Assisted reproductive technology" (ART), with its grammatical variations and cognate expressions, means all techniques that attempt to obtain a pregnancy by handling or manipulating the sperm or the oocyte outside the human body, and transferring the gamete or the embryo into the reproductive tract;

# **Terminology**

- "Assisted reproductive technology clinic", means any premises used for procedures related to assisted reproductive technology;
- "biological parent(s)", means genetic parent(s);
- "child", means any individual born through the use of assisted reproductive technology;
- "Commissioning parents / couples / Individuals", means parents, couples or individuals, respectively, who approach an ART clinics or ART bank
- "cryo-preservation", means the freezing and storing of gametes, zygotes and embryos;
- "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;
- "egg", means the female gamete (that is, oocyte)
- "embryo", means the fertilized ovum that has begun cellular division and continued development up to eight weeks
- "gamete donor", means a person who provides sperm or oocyte with the objective of enabling an infertile couple or individual to have a child

### Steps Involved in the Functioning of the sperm bank

#### 1. Recruitment

The finding of a potential sperm donor and motivating him to actually donate sperm is typically called recruitment.

Mode of Advertising?

A donor must be a fit healthy male, normally between 21 to 45 years of age, who is willing to undergo frequent and rigorous testing and who is willing to donate his sperm so that it can be used to impregnate women who are unrelated to, and unknown by, him. The donor must agree to relinquish all legal rights to all children which result from his donations. The donor must produce his sperm at the sperm bank thus enabling the identity of the donor.

#### 2. Screening of donors

A sperm donor must generally meet specific requirements regarding age and medical history.

Sperm banks typically screen potential donors for a range of diseases and disorders, including genetic diseases, chromosomal abnormalities and sexually transmitted infections that may be transmitted through sperm. A sperm bank takes a number of steps to ensure the health and quality of the sperm which it supplies and it will inform customers of the checks which it undertakes, providing relevant information about individual donors.

## Do we have a consensus?

- A sperm bank will usually guarantee the quality and number of motile sperm available in a sample after thawing. Consensus on Quarantine of semen samples?
- Is Karyotyping compulsory?
- Should Sperm banks provide nutritional Supplements to the donors to improve the quality of sperm?
- Sperm Donor payment- should we pay or should it be an Altruistic act?

## Information about donor

- What should be permitted and what should not be disclosed?
- Should sperm banks maintain lists or catalogs of donors which provide basic information about the donor such as racial origin, skin color, height, weight, colour of eyes, and blood group. Some of these catalogs are available for browsing on the Internet, while others are made available to patients only when they apply to a sperm bank for treatment.

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

- 1. The screening of gamete donors and surrogates; the collection, screening and storage of semen; and provision of oocyte donor and surrogates, shall be done by an ART bank registered as an independent entity under the provisions of this Act.
- An ART bank shall operate independently of any assisted reproductive technology clinic.
- 3. ART banks shall obtain semen from males between twenty one years of age and forty five years of age, both inclusive, and arrange to obtain oocytes from females between twenty one years of age and thirty five years of age, both inclusive, and examine the donors for such diseases, sexually transmitted or otherwise, as may be prescribed, and all other communicable diseases which may endanger the health of the parents, or any one of them, surrogate or child.

- 4. All ART banks shall have standard, scientifically established facilities and defined standard operating procedures for all its scientific and technical activities.
- 5. All ART banks shall cryo-preserve sperm donations for a quarantine period of at least six months before being used and, at the expiry of such period, the ART bank shall not supply the sperm to any assisted reproductive technology clinic unless the sperm donor is tested for such diseases, sexually transmitted or otherwise, as may be prescribed.
- 6. An ART bank may advertise for gamete donors and surrogates, who may be compensated financially by the bank.

- 7. An ART bank shall not supply the sperm of a single donor for use more than seventy five times.
- 8. No woman shall donate oocytes more than six times in her life, with not less than a three-month interval between the oocyte pick-ups.
- Eggs from one donor can be shared between two recipients only, provided that at least seven oocytes are available for each recipient.
- 10. All unused oocytes would be either appropriately preserved by the assisted reproductive technology clinic for use on the same recipient(s), or given for research to a bonafide organisation.

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

### Storage and handling of gametes and embryos

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

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

### Records to be maintained by the ART bank

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

#### 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.

# Rights and duties of donors

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

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

- 6. Any woman seeking or agreeing to act as a surrogate mother shall be medically tested for such diseases, sexually transmitted or otherwise, as may be prescribed, and all other communicable diseases which may endanger the health of the child, and must declare in writing that she has not received a blood transfusion or a blood product in the last six months.
- 7. Individuals or couples may obtain the service of a surrogate through an ART bank, which may advertise to seek surrogacy provided that no such advertisement shall contain any details relating to the caste, ethnic identity or descent of any of the parties involved in such surrogacy. No assisted reproductive technology clinic shall advertise to seek surrogacy for its clients.
- 8. A surrogate mother shall, in respect of all medical treatments or procedures in relation to the concerned child, register at the hospital or such medical facility in her own name, clearly declare herself to be a surrogate mother, and provide the name or names and addresses of the person or persons, as the case may be, for whom she is acting as a surrogate, along with a copy of the certificate mentioned in clause 17 below.
- 9. If the first embryo transfer has failed in a surrogate mother, she may, if she wishes, decide to accept on mutually agreed financial terms, at 27most two more successful embryo transfers for the same couple that had engaged her services in the first instance. No surrogate mother shall undergo embryo transfer more than three times for the same couple.
- 10. The birth certificate issued in respect of a baby born through surrogacy shall bear the name(s) of individual / individuals who commissioned the surrogacy, as parents.

- 11. The person or persons who have availed of the services of a surrogate mother shall be legally bound to accept the custody of the child / children irrespective of any abnormality that the child / children may have, and the refusal to do so shall constitute an offence under this Act.
- 12. Subject to the provisions of this Act, all information about the surrogate shall be kept confidential and information about the surrogacy shall not be disclosed to anyone other than the central database of the Department of Health Research, except by an order of a court of competent jurisdiction.
- 13. A surrogate mother shall not act as an oocyte donor for the couple or individual, as the case may be, seeking surrogacy.
- 14. No assisted reproductive technology clinic shall provide information on or about surrogate mothers or potential surrogate mothers to any person.
- 15. Any assisted reproductive technology clinic acting in contravention of sub-section 14 of this section shall be deemed to have committed an offence under this Act.

- 16. In the event that the woman intending to be a surrogate is married, the consent of her spouse shall be required before she may act as such surrogate.
- 17. A surrogate mother shall be given a certificate by the person or persons who have availed of her services, stating unambiguously that she has acted as a surrogate for them.
- 18. A relative, a known person, as well as a person unknown to the couple may act as a surrogate mother for the couple/individual. In the case of a relative acting as a surrogate, the relative should belong to the same generation as the women desiring the surrogate.
- 19. A foreigner or foreign couple not resident in India, or a non-resident Indian individual or couple, seeking surrogacy in India shall appoint a local guardian who will be legally responsible for taking care of the surrogate during and after the pregnancy as per clause 34.2, till the child / children are delivered to the foreigner or foreign couple

#### Right of the child to information about donors or surrogates

- 1. A child may, upon reaching the age of 18, ask for any information, excluding personal identification, relating to the donor or surrogate mother.
- 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.
- 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.

### Punishment proposed for violations

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 31Misuse) 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.

- 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.
- 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.
- Use of individual brokers or paid intermediaries to obtain gamete donors or surrogates shall be an offence under this Act, punishable by imprisonment for a term which may extend to three years and fine which may be specified.

- 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.
- 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.