

Chapter 3

Code of Practice, Ethical Considerations and Legal Issues

3.1 Clinics which should be Licensed

Clinics involved in any one of the following activities should be regulated, licensed and supervised by the accreditation authority.

1. Any treatment involving the use of gametes which have been donated or collected or processed *in vitro*, *except for* AIH, and for IUI by level 1A clinics who will not process the gametes themselves.
2. Any infertility treatment that involves the use and creation of embryos outside the body.
3. The processing or /and storage of gametes or embryos.
4. Research on human embryos.

The term ART clinic used in this document refers to a clinic involved in any one of the first three of the above activities.

3.2 Code of Practice

This Code of Practice deals with all aspects of the treatment provided and the research done at licensed clinics. Those areas which most affect the doctors, scientists and patients and are a part of this code are summarized below.

3.2.1 Staff: A ‘person responsible’ shall take full responsibility for ensuring that the staff of the licensed unit is sufficiently qualified, that proper equipment is used, that genetic material is kept and disposed off properly, and that the center complies with the conditions of its license. *Guidelines for minimum standards* and qualifications of clinical, scientific and counselling staffs are laid down in Chapter 1. Failure of the ‘person responsible’ to comply with the *mandatory code of practice* can lead to his/her removal or prosecution, or to the suspension of the clinic’s license.

- 3.2.2 Facilities:** These must cover the standards expected in respect of provision of clinical, laboratory and counselling care mentioned in Chapters 1 and 2. Proper systems for monitoring and assessing practices and procedures are required to be in place (for example in the form of Standard Operating Procedures) in order to optimize the outcome of ART.
- 3.2.3 Confidentiality:** Any information about clients and donors must be kept confidential. No information about the treatment of couples provided under a treatment agreement may be disclosed to anyone other than the accreditation authority or persons covered by the license, except with the consent of the person(s) to whom the information relates, or in a medical emergency concerning the patient, or a court order. It is the above person's right to decide what information will be passed on and to whom, except in the case of a court order.
- 3.2.4 Information to patient:** All relevant information must be given to the patient before a treatment is given. Thus, before starting treatment, information should be given to the patient on the limitations and results of the proposed treatment, possible side-effects, the techniques involved, comparison with other available treatments, the availability of counselling, the cost of the treatment, the rights of the child born through ART, and the need for the clinic to keep a register of the outcome of a treatment.
- 3.2.5 Consent:** No treatment should be given without the written consent of the couple to all the possible stages of that treatment, including the possible freezing of supernumerary embryos. A standard consent form recommended by the accreditation authority should be used by all ART clinics. Specific consent must be obtained from couples who have their gametes or embryos frozen, in regard to what should be done with them if he/she dies, or becomes incapable of varying or revoking his or her consent.

3.2.6 Counselling: People seeking licensed treatment must be given a suitable opportunity to receive proper counselling about the various implications of the treatment. No one is obliged to accept counselling but it is generally recognized as being beneficial, and couples should be encouraged to go through it. The provision of facilities for counselling in an ART clinic (of Levels 1B, 2 or 3) is, therefore, mandatory. Couples should be referred for support or therapeutic counselling as appropriate.

3.2.7 Use of gametes and embryos: No more than three oocytes or embryos may be placed in a woman in any one cycle, regardless of the procedure/s used, excepting under exceptional circumstances (such as elderly women, poor implantation, adenomiosis, or poor embryo quality) which should be recorded. No woman should be treated with gametes or with embryos derived from the gametes of more than one man or woman during any one-treatment cycle.

3.2.8 Storage and handling of gametes and embryos: The ‘highest possible standards’ in the storage and handling of gametes and embryos in respect of their security, and in regard to their recording and identification, should be followed.

3.2.9 Research: The accreditation authority must approve all research that involves embryos created *in vitro*. A separate license should be issued for each research project involving human embryos. The accreditation authority must not give a license unless it is satisfied that the use of human embryos is essential for the purposes of the proposed research and the research is in public interest.

Additionally:

- (i) No human embryo may be placed in a non-human animal
- (ii) All research projects must be approved by the Institutional Ethics Committee before submission to the accreditation authority.

3.2.10 Complaints: All licensed ART clinics are required to have procedures for acknowledging and investigating complaints, and to have a nominated person to deal properly with such complaints. The accreditation authority must be informed of the number of complaints made in any year and those that are outstanding.

3.3 Responsibilities of the Clinic

- 3.3.1** To give adequate information to the patients (detailed in Section 3.4).
- 3.3.2** To explain to the patient the rationale of choosing a particular treatment (see Chapter 2) and indicate the choices the patient has (including the cheapest possible course of treatment), with advantages and disadvantages of each choice.
- 3.3.3** To help the patient exercise a choice, which may be best for him/her, taking into account the individual's circumstances.
- 3.3.4** To maintain records in an appropriate proforma (to be prescribed by the authority) to enable collation by a national body.
- 3.3.5** When commercial DNA fingerprinting becomes available, to keep on its record, if the ART clinic desires and couple agrees, DNA fingerprints of the donor, the child, the couple and the surrogate mother should be done.
- 3.3.6** To keep all information about donors, recipients and couples confidential and secure. The information about the donor (including a copy of the donor's DNA fingerprint if available, but excluding information on the name and address – that is, the individual's personal identity) should be released by the ART clinic after appropriate identification, only to the offspring and only if asked by him/her after he/she reaches the age of 18 years, or as and when specified and required for legal purposes, and never to the parents (excepting when directed by a court of law).

- 3.3.7** To maintain appropriate, detailed record of all donor oocytes, sperm or embryos used, the manner of their use (e.g. the technique in which they are used, and the individual/couple/surrogate mother on whom they are used). These records must be maintained for at least ten years after which the records must be transferred to a central depository to be maintained by the ICMR. If the ART clinic/centre is wound up during this period, the records must be transferred to the central repository in the ICMR.
- 3.3.8** To have the schedule of all its charges suitably displayed in the clinic and made known to the patient at the beginning of the treatment. There must be no extra charges beyond what was intimated to the patient at the beginning of the treatment.
- 3.3.9** To ensure that no technique is used on a patient for which demonstrated expertise does not exist with the staff of the clinic.
- 3.3.10** To be totally transparent in all its operations. The ART clinics must, therefore, let the patient know what the success rates of the clinic are in regard to the procedures intended to be used on the patient.
- 3.3.11** To have all consent forms available in English and local language(s).

3.4 Information and Counselling to be given to Patients

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

- 3.4.1.** 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).
- 3.4.2.** 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.

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- 3.4.3** The need to reduce the number of viable foetuses, in order to ensure the survival of at least two foetuses.
 - 3.4.4.** Possible disruption of the patient’s domestic life which the treatment may cause.
 - 3.4.5** The techniques involved, including (where relevant) the possible deterioration of gametes or embryos associated with storage, and possible pain and discomfort.
 - 3.4.6** 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”).
 - 3.4.7** The importance of informing the clinic of the result of the pregnancy in a pre-paid envelope.
 - 3.4.8** To make the couple aware, if relevant, that a child born through ART has a right to seek information (including a copy of the DNA fingerprint, if available) 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.
 - 3.4.9** The advantages and disadvantages 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.

3.5 Desirable Practices/Prohibited Scenarios

- 3.5.1** A third party donor of sperm or oocytes must be informed that the offspring will not know his/her identity. He/She must also be informed of the provisions in Section 3.4.8.
- 3.5.2** There would be no bar to the use of ART by a single women who wishes to have a child, and no ART clinic may refuse to offer its services to the above, provided other criteria mentioned in this document are satisfied. The child thus born will have all the legal rights on the woman or the man.
- 3.5.3** The ART clinic must not be a party to any commercial element in donor programmes or in gestational surrogacy.
- 3.5.4** A surrogate mother carrying a child biologically unrelated to her must register as a patient in her own name. While registering she must mention that she is a surrogate mother and provide all the necessary information about the genetic parents such as names, addresses, etc. She must not use/register in the name of the person for whom she is carrying the child, as this would pose legal issues, particularly in the untoward event of maternal death (in whose names will the hospital certify this death?). The birth certificate shall be in the name of the genetic parents. The clinic, however, must also provide a certificate to the genetic parents giving the name and address of the surrogate mother. All the expenses of the surrogate mother during the period of pregnancy and post-natal care relating to pregnancy should be borne by the couple seeking surrogacy. The surrogate mother would also be entitled to a monetary compensation from the couple for agreeing to act as a surrogate; the exact value of this compensation should be decided by discussion between the couple and the proposed surrogate mother. An oocyte donor can act as a surrogate mother.
- 3.5.5** A third-party donor and a surrogate mother must relinquish in writing all parental rights concerning the offspring and vice versa.

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- 3.5.6** No ART procedure shall be done without the spouse's consent.
- 3.5.7** The provision or otherwise of AIH or ART to an HIV-positive woman would be governed by the implications of the decision of the Supreme Court in the case of X – vs – Hospital 2 (1998) 8 Sec. 269 or any other relevant judgement of the Supreme Court, or law of the country, whichever is the latest.
- 3.5.8** Gametes produced by a person under the age of 21 shall not be used. The accepted age for a sperm donor shall be between 21 and 45 years and for the donor woman between 18 and 35 years.
- 3.5.9** Sex selection at any stage after fertilization, or abortion of foetus of any particular sex should not be permitted, except to avoid the risk of transmission of a genetic abnormality assessed through genetic testing of biological parents or through preimplantation genetic diagnosis (PGD).
- 3.5.10** No ART clinic shall offer to provide a couple with a child of the desired sex.
- 3.5.11** Collection of gametes from a dying person will only be permitted if the widow wishes to have a child.
- 3.5.12** No more than three eggs or embryos should be placed in a woman during any one treatment cycle, regardless of the procedure used, excepting under exceptional circumstances {such as elderly women (above 37 years), poor implantation (more than three previous failures), advanced endometriosis, or poor embryo quality} which should be recorded.
- 3.5.13** Use of sperm donated by a relative or a known friend of either the wife or the husband shall not be permitted. It will be the responsibility of the ART clinic to obtain sperm from appropriate banks; neither the clinic nor the couple shall have the right to know the donor identity and address, but both the clinic and the couple, however, shall have the right to have the fullest possible information from the semen bank on the donor such as height, weight, skin

colour, educational qualification, profession, family background, freedom from any known diseases or carrier status (such as hepatitis B or AIDS), ethnic origin, and the DNA fingerprint (if possible), before accepting the donor semen. It will be the responsibility of the semen bank and the clinic to ensure that the couple does not come to know the identity of the donor. The ART clinic will be authorized to appropriately charge the couple for the semen provided and the tests done on the donor semen.

- 3.5.14** What has been said above under 3.5.13 also would be true of oocyte donation.
- 3.5.15** When DNA fingerprinting technology becomes commercially available, the ART clinic may offer to the couple, a DNA fingerprint of the donor without revealing his/her identity, against appropriate payment towards the cost of the DNA fingerprint. An ART clinic will then have DNA fingerprinting done of the couple and keep the DNA fingerprints on its records.
- 3.5.16** Trans-species fertilization involving gametes of two species is prohibited.
- 3.5.17** Ova derived from foetuses cannot be used for IVF but may be used for research.
- 3.5.18** Semen from two individuals must never be mixed before use, under any circumstance.
- 3.5.19** Transfer of human embryo into a human male or into any animal belonging to any other species, must never be done and is prohibited.
- 3.5.20** The data of every accredited ART clinic must be accessible to an appropriate authority of the ICMR for collation at the national level.
- 3.5.21** Any publication or report resulting out of analysis of such data by the ICMR will have the concerned members of the staff of the ART clinic as co-authors.

- 3.5.22** The consent on the consent form must be a true informed consent witnessed by a person who is in no way associated with the clinic.

3.6 Requirements for a Sperm Donor

- 3.6.1** The individual must be free of HIV and hepatitis B and C infections, hypertension, diabetes, sexually transmitted diseases, and identifiable and common genetic disorders such as thalassemia.
- 3.6.2** The age of the donor must not be below 21 or above 45 years.
- 3.6.3** An analysis must be carried out on the semen of the individual, preferably using a semen analyzer, and the semen must be found to be normal according to WHO method manual for semen analysis, if intended to be used for ART.
- 3.6.4** The blood group and the Rh status of the individual must be determined and placed on record.
- 3.6.5** 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, and the family background in respect of history of any familial disorder, must be recorded in an appropriate proforma.

3.7 Requirements for an Oocyte Donor

- 3.7.1** The individual must be free of HIV and hepatitis B and C infections, hypertension, diabetes, sexually transmitted diseases, and identifiable and common genetic disorders such as thalassemia.
- 3.7.2** The blood group and the Rh status of the individual must be determined and placed on record.
- 3.7.3** Other relevant information in respect of the donor, such as height, weight, age, educational qualifications, profession, colour of the skin and the eyes, and the family background in respect of history of any familial disorder, must be recorded in an appropriate proforma.

- 3.7.4** The age of the donor must not be less than 21 or more than 35 years.

3.8 Requirements for a Surrogate Mother

See Section 3.10.

3.9 How may Sperm and Oocyte Donors and Surrogate Mothers be Sourced?

3.9.1 Semen banks

- 3.9.1.1** Either an ART clinic or a law firm or any other suitable independent organization may set up a semen bank. If set up by an ART clinic it must operate as a separate identity.
- 3.9.1.2** The bank will ensure that all criteria mentioned in Section 3.6 (Requirements for a sperm donor) are met and a suitable record of all donors is kept for 10 years after which, or if the bank is wound up during this period, the records shall be transferred to an ICMR repository.
- 3.9.1.3** A bank may advertise suitably for semen donors who may be appropriately compensated financially.
- 3.9.1.4** On request for semen by an ART clinic, the bank will provide the clinic with a list of donors (without the name or the address but with a code number) giving all relevant details such as those mentioned in Section 3.6. The semen bank shall not supply semen of one donor for more than ten successful pregnancies. It will be the responsibility of the ART clinic or the patient, as appropriate, to inform the bank about a successful pregnancy. The bank shall keep a record of all semen received, stored and supplied, and details of the use of the semen of each donor. This record will be liable to be reviewed by the accreditation authority.

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- 3.9.1.5** The bank must be run professionally and must have facilities for cryopreservation of semen, following internationally accepted protocols. Each bank will prepare its own SOP (Standard Operating Procedures) for cryopreservation.
- 3.9.1.6** Semen samples must be cryopreserved for at least six months before first use, at which time the semen donor must be tested for HIV and hepatitis B and C.
- 3.9.1.7** The bank must ensure confidentiality in regard to the identity of the semen donor.
- 3.9.1.8** A semen bank may store a semen preparation for exclusive use on the donor's wife or on any other woman designated by the donor. An appropriate charge may be levied by the bank for the storage. In the case of non-payment of the charges when the donor is alive, the bank would have the right to destroy the semen sample or give it to a bonafide organisation to be used only for research purposes. In the case of the death of the donor, the semen would become the property of the legal heir or the nominee of the donor at the time the donor gives the sample for storage to the bank. All other conditions that apply to the donor would now apply to the legal heir, excepting that he cannot use it for having a woman of his choice inseminated by it. If after the death of the donor, there are no claimants, the bank would have the right to destroy the semen or give it to a bonafide research organisation to be used only for research purposes.
- 3.9.1.9** All semen banks will require accreditation.

3.9.2. Sourcing of oocytes and surrogate mothers

Law firms and semen banks will be encouraged to obtain (for example, through appropriate advertisement) and maintain information on possible oocyte donors and surrogate mothers as per details mentioned elsewhere in this document. The above organizations may appropriately charge the couple for providing an oocyte or a surrogate mother. The oocyte

donor may be compensated suitably (e.g. financially) by the law firm or semen bank when the oocyte is donated. However, negotiations between a couple and the surrogate mother must be conducted independently between them.

3.9.3. Oocyte sharing

The system of oocyte sharing in which an indigent infertile couple that needs to raise resources for ART agrees to donate oocytes to an affluent infertile couple wherein the wife can carry a pregnancy through but cannot produce her own oocyte, for in-vitro fertilization with the sperm of the male partner of the affluent couple, for a monetary compensation that would take care of the expenses of an ART procedure on the indigent couple, must be encouraged.

3.10 Surrogacy: General Considerations

- 3.10.1** A child born through surrogacy must be adopted by the genetic (biological) parents unless they can establish through genetic (DNA) fingerprinting (of which the records will be maintained in the clinic) that the child is theirs.
- 3.10.2** Surrogacy by assisted conception should normally be considered only for patients for whom it would be physically or medically impossible/undesirable to carry a baby to term.
- 3.10.3** Payments to surrogate mothers should cover all genuine expenses associated with the pregnancy. Documentary evidence of the financial arrangement for surrogacy must be available. The ART centre should not be involved in this monetary aspect.
- 3.10.4** Advertisements regarding surrogacy should not be made by the ART clinic. The responsibility of finding a surrogate mother, through advertisement or otherwise, should rest with the couple, or a semen bank (see 3.9.1.1; 3.9.2).

- 3.10.5** A surrogate mother should not be over 45 years of age. Before accepting a woman as a possible surrogate for a particular couple's child, the ART clinic must ensure (and put on record) that the woman satisfies all the testable criteria to go through a successful full-term pregnancy.
- 3.10.6** 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.
- 3.10.7** A prospective surrogate mother must be tested for HIV and shown to be seronegative for this virus just before embryo transfer. She must also provide a written certificate that (a) she has not had a drug intravenously administered into her through a shared syringe, (b) she has not undergone blood transfusion; and (c) she and her husband (to the best of her/his knowledge) has had no extramarital relationship in the last six months. (This is to ensure that the person would not come up with symptoms of HIV infection during the period of surrogacy.) The prospective surrogate mother must also declare that she will not use drugs intravenously, and not undergo blood transfusion excepting of blood obtained through a certified blood bank.
- 3.10.8** No woman may act as a surrogate more than thrice in her lifetime.

3.11 Preservation, Utilization & Destruction of Embryos

- 3.11.1** Couples must give specific consent to storage and use of their embryos. The Human Fertilization & Embryology Act, UK (1990), allows a 5-year storage period which India would also follow.
- 3.11.2** Consent shall need to be taken from the couple for the use of their stored embryos by other couples or for research, in the event of their embryos not being used by themselves. This consent will not

be required if the couple defaults in payment of maintenance charges after two reminders sent by registered post.

- 3.11.3** Research on embryos shall be restricted to the first fourteen days only and will be conducted only with the permission of the owner of the embryos.
- 3.11.4** No commercial transaction will be allowed for the use of embryos for research.

3.12 Rights of a Child Born through various ART Technologies

- 3.12.1** A child born through ART shall be presumed to be the legitimate child of the couple, having been born in wedlock and with the consent of both the spouses. Therefore, the child shall have a legal right to parental support, inheritance, and all other privileges of a child born to a couple through sexual intercourse.
- 3.12.2** Children born through the use of donor gametes, and their “adopted” parents shall have a right to available medical or genetic information about the genetic parents that may be relevant to the child’s health.
- 3.12.3** Children born through the use of donor gametes shall not have any right whatsoever to know the identity (such as name, address, parentage, etc.) of their genetic parent(s). A child thus born will, however, be provided all other information (including that mentioned in Section 3.4.8) about the donor as and when desired by the child, when the child becomes an adult. While the couple will not be obliged to provide the above “other” information to the child on their own, no deliberate attempt will be made by the couple or others concerned to hide this information from the child as and when asked for by the child.
- 3.12.4** In the case of a divorce during the gestation period, if the offspring is of a donor programme – be it sperm or ova – the law of the land as pertaining to a normal conception would apply.

3.13 Responsibilities of the Drug Industry

- 3.13.1** Drug companies must not make exaggerated claims for infertility drugs and market them only to qualified specialists. All available information on the drug must be provided to the specialist.
- 3.13.2** Infertility drugs must be sold only on prescription by a qualified doctor/ART specialist.
- 3.13.3** There has been a spurt of new media introduced for *in vitro* culture of gametes and embryos. Companies dealing with culture media do not give full details of the composition because they wish to retain this as a trade secret. This poses problems for those dealing with human embryos. The future life of the products created in the laboratory is dependant, to a certain extent, on the culture media used. ART centers should not encourage companies that do not give details of the full composition of the culture media. This will also make it possible to take legal action against a company supplying something different from what it is stated to be.

3.14 General Considerations

3.14.1 Minimum age for ART:

For a woman between 20 and 30 years, two years of cohabitation/marriage without the use of a contraceptive, excepting in cases where the man is infertile or the woman cannot physiologically conceive. For a woman over 30 years, one year of cohabitation/marriage without use of contraceptives. Normally, no ART procedure shall be used on a woman below 20 years.

3.14.2 Advertisements of an infertility centre:

False claims via hoardings and paper advertisements are a cheap way of attracting a clientele that is vulnerable and, therefore, easily swayed. Such advertisements shall be banned. An honest display at appropriate places or publicity of statistics, fee structure, quality

of service and of service provided, will be encouraged, provided the guidelines laid down by the Medical Council of India in this regard, are not violated.

3.14.3 Reimbursement of infertility treatment: role of insurance:

In India, infertile couples are considered to be an accursed lot. Couples will go to any extent to bear a child, sometimes selling all they have. Keeping in mind the societal pressures, there is an urgent need to have infertility treated like any other disease the expense of dealing with which by authorized ART clinics should be reimbursable, e.g. by the Government or other employer or by the health insurance company, but for one child only. Appropriate steps shall be taken by those concerned in this regard.

3.14.4 As already mentioned, sperm banks where a complete assessment of the donor has been done, medical and other vital information stored, quality of preservation ensured, confidentiality assured, and strict control exercised by a regulatory body, must be set up. Donor sperm would be made available only through such specialized banks/centers.

3.14.5 In the light of a recent technological breakthrough where a fertilized ovum containing ooplasm (including mitochondria) from a donor ovum has been successfully cultured, the embryo or the future child may now have three genetic parents. In such cases, the ooplasm donor must sign a waiver relinquishing all rights on the child, and must be screened for and declared free of known mitochondrial genetic abnormalities.

3.14.6 No new ART clinic may start operating unless it has obtained a temporary license to do so. This license would be confirmed only if the clinic obtains accreditation (permanent license) from the Center or State's appropriate accreditation authority within two years of obtaining the temporary license. The license must be renewed every seven years.

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- 3.14.7** Existing ART clinics must obtain a temporary license within six months of the notification of the accreditation authority, and appropriate accreditation (permanent license) within two years of the notification.
- 3.14.8** The Center/State Government would close down any unlicensed clinic not satisfying the above criteria.
- 3.14.9** If the ART clinic that has applied for a temporary license to the appropriate accreditation authority, does not receive the license (or a reply) within two months of the receipt of the application from the concerned office of the authority, the ART clinic would be deemed to have received the license. The same would apply for the permanent license after the above-prescribed period.
- 3.14.10** As pointed out in section 1.6.12.2, the technique of ICSI has never undergone critical testing in animal models, but was introduced into the human situation directly. Defects in spermatogenesis and sperm production can be often traced to genetic defects. Such individuals are normally prevented from transmitting these defects to their offspring because of their natural infertility. ICSI by-passes this barrier and may help in transmitting such defects to the offspring, which sometimes may be exaggerated in the offspring. In view of this, the ART clinic must point out to the prospective parents that their child born through ICSI may have a slightly higher risk over and above the normal risk, of suffering from a genetic disorder.
- 3.14.11** Human cloning for delivering replicas must be banned.
- 3.14.12** Stem cell cloning and research on embryos (less than 15 days old) needs to be encouraged.
- 3.14.13** All the equipments/machines should be calibrated regularly.

3.15 Responsibilities of the Accreditation Authority

An accreditation authority will be set up by the Ministry of Health and Family Welfare, Government of India, which shall, in turn, set up, a National Accreditation Committee and a committee (Review Committee) which would have the statutory right to visit individually or collectively, any ART clinic/centre(s) (accredited or not accredited) once a year with or without prior information to the clinic/centre, to determine if the ethical guidelines and operative procedures mentioned here are being followed. If not, the Review Committee will point out the lapses to the clinic/centre in writing. If these lapses continue for a maximum period of six months (during which period the clinic shall not engage in any activity related to the lapse), the Review Committee would recommend to the Accreditation Authority, through the National Accreditation Committee, that the clinic/centre may be ordered to be closed. The Accreditation Authority will have the powers to order the closing of such a clinic or centre, while the National Accreditation Committee will have the powers to impose a fine or a penalty on the clinic or the centre.

The above Review Committee, which would consist of appropriately qualified scientists, technologists and sociologists, will also be authorized to visit and regulate semen banks in the manner mentioned above.

Since one set of the above-mentioned two committees may not be able to serve the entire country, a State may set up, through its Department of Health and/or Family Welfare, its own committees along the lines of the above-mentioned central committees, including a minimum of one representative from or nominee of the central committee. The powers of the two State committees will be the same as of the corresponding national committees.

The National Accreditation Authority will have the right and the responsibility of fixing the upper limit of charges for gamete donation and surrogacy and of revising these charges from time to time.

In case of an undue and reasonable difficulty in fulfilling any of the obligations of the document, the management of the concerned infertility clinic or ART center may bring the matter to the notice of the concerned committee for advise and/or decision.

The appellate authority for a decision of the National Accreditation Committee, would be the Accreditation Authority, and for a decision of the Accreditation Authority, the Supreme Court. The appellate authority for a State-level Accreditation Committee would be the National Accreditation Committee.

The National Accreditation Committee shall have the power to (a) lay down specifications, qualifications, or criteria, where not mentioned in the Guidelines; and (b) charge or modify specifications, qualifications or criteria mentioned in the Guidelines, with the approval of the Accreditation Authority.

3.16 Legal Issues

3.16.1 Legitimacy of the child born through ART

A child born through ART shall be presumed to be the legitimate child of the couple, born within wedlock, with consent of both the spouses, and with all the attendant rights of parentage, support and inheritance. Sperm/oocyte donors shall have no parental right or duties in relation to the child, and their anonymity shall be protected except in regard to what is mentioned under item 3.12.3.

3.16.2 Adultery in the case of ART

ART used for married woman with the consent of the husband does not amount to adultery on part of the wife or the donor. AID without the husband's consent can, however, be a ground for divorce or judicial separation.

3.16.3 Consummation of marriage in case of AIH

Conception of the wife through AIH does not necessarily amount to consummation of marriage and a decree of nullity may still be granted in favor of the wife on the ground of impotency of the husband or his willful refusal to consummate the marriage. However, such a decree could be excluded on the grounds of approbation.

3.16.4 Rights of an unmarried woman to AID

There is no legal bar on an unmarried woman going for AID. A child born to a single woman through AID would be deemed to be legitimate. However, AID should normally be performed only on a married woman and that, too, with the written consent of her husband, as a two-parent family would be always better for the child than a single parent one, and the child's interests must outweigh all other interests.

3.16.5 Posthumous AIH through a sperm bank

Though the Indian Evidence Act, 1872, says that a child born within 280 days after dissolution of marriage (by death or divorce) is a legitimate child since that is considered to be the gestation period, it is pertinent to note that this Act was enacted as far back as 1872 when one could not even visualize ART. The law needs to take note of the scientific advancements since that time. Thus a child born to a woman artificially inseminated with the stored sperms of her deceased husband must be considered to be a legitimate child notwithstanding the existing law of presumptions under our Evidence Act. The law needs to move along with medical advancements and suitably amended so that it does not give rise to dilemma or unwarranted harsh situations.

3.17 Institutional Ethics Committees

Each ART clinic of Levels 1B, 2 and Level 3 must have its own ethics committee constituted according to ICMR Guidelines, comprising reputed ART practitioners, scientists who are knowledgeable in

developmental biology or in clinical embryology, a social scientist, a member of the judiciary and a person who is well-versed in comparative theology. Should the local ART clinic have difficulty in establishing such a body, the accreditation authority should constitute such a body, co-opting a representative of the ART clinic.