

Draft

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



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



**INDIAN COUNCIL OF MEDICAL RESEARCH
NEW DELHI**

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

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Contents

ASSISTED REPRODUCTIVE TECHNOLOGY (REGULATION) Rules - 2010

1.	Short Title and Commencement	1
2.	Definition	1
3.	Categories of Infertility / ART Clinics	1
4.	Minimum Requirement Regarding Staff in Infertility Clinics	1
5.	Minimum Physical Infrastructure Requirement for an Infertility Clinic	1
6.	ART Procedures	2
7.	Patient Selection	2
8.	Selection Criteria for ART Procedure	2
9.	Information, Advice and Counselling to Patients	2
10.	Registration of ART Clinics, Semen Banks and Research Centers using Human Embryos	2
11.	Application Fee	2
12.	Certificate of Registration	3
13.	Validity of Registration	4
14.	Renewal of Registration	4
15.	Consents, Agreements & Contracts for Conducting ART Procedures	5
16.	Facilities for Inspection	6
17.	Public Information	6
SCHEDULE – I		
<u>PART – 1</u>		7-9
1.	Primary (Level 1) Infertility Clinics	7
1.2	Secondary (Level 2) Infertility Clinics	8
1.3	Tertiary (Level 3) Infertility Clinics	9
<u>PART – 2</u>		10-13
2.	Minimum Requirement Regarding Staff in Infertility Clinics	10
2.1.	Gynaecologist	10
2.2	Andrologist	11
2.3	Clinical Embryologist	12
2.4	Counsellor	13
2.5	Programme Co-ordinator / Director	13
<u>PART – 3</u>		13-18
3.	Minimal Physical Requirements for an ART Clinic	13
3.1	The non-sterile area	14
3.2.	A reception and waiting room for patients	14
3.3	An examination room with privacy	14
3.4	A general-purpose clinical laboratory	14
3.5	Store room	14
3.6	Record room	14
3.7	Autoclave room	14
3.8	Steps for vermin proofing	15
3.9	Semen collection room	15

3.10	Semen processing laboratory	15
3.11	Clean room for IUI	15
3.12	The sterile area	15
3.13	The operation theatre	15
3.14	Room for embryo transfer	16
3.15	The embryology laboratory complex	16
3.16	Ancillary laboratory facilities	16
3.17	Hormone and other assays	17
3.18	Microbiology and histopathology	17
3.19	Maintenance of the laboratories	17
3.20	Quality of consumables used in the laboratory	17
3.21	Back-up power supply	18

PART – 4 **18-23**

4. Assisted Reproductive Technology (ART) Procedures: **18**

4.1	Artificial insemination with husband's semen (AIH)	18
4.2	Artificial insemination with donor semen (AID)	18
4.3.	Intrauterine insemination with either husband's or donor semen (IUI-H or IUI-D)	19
4.4.	In vitro fertilization and embryo transfer (IVF-ET)	19
4.5	IVF associated techniques	19
4.6	Intracytoplasmic sperm injection (ICSI) with ejaculated, epididymal or testicular spermatozoa	20
4.7	Oocyte donation (OD) or embryo donation (ED)	21
4.8	Cryopreservation	22
4.9	In vitro culture media	23

PART – 5 **23-25**

5. Patient Selection **23**

5.1	Husband	23
5.2	Wife	24
5.3	Patient selection for treatment in different infertility care units	24
5.4	Single defect in one of the partner	25
5.5	Multiple defects in one or both partners	25

PART – 6 **25-28**

6. Selection criteria for ART **25**

6.1	Tubal disease	25
6.2	Endometriosis	26
6.3	Unexplained infertility	26
6.4	Immunological factor	26
6.5	Cervical factor	26
6.6	Male factor	26
6.7	Ovarian disorders	26
6.8	Uterine disorders	26
6.9	Use of donor oocytes and donor embryos	27
6.10	Selection criteria for gamete intra-fallopian transfer (GIFT)	27
6.11	Choosing between IVF-ET and GIFT	27
6.12	Micro-manipulation of gametes and embryos (SUZI and ICSI), AH and embryo biopsy	27

6.13	Complications	28
<u>PART – 7</u>		29-86
7	Information and counselling to be given to patients	29
FORM – A	Form of Application for Registration or Renewal of Registration of an Infertility/Art Clinic	30
FORM – A1	Form of Application for Registration or Renewal of Registration of an ART Bank	33
FORM – A2	Form of Application for Registration or Renewal of Registration of a Research Centre using Human Embryos	36
FORM – B	Certificate of Registration	39
FORM – C	Rejection of Application for Registration or Renewal of Registration	40
FORM – D	Consent Form to be signed by the Couple for IVF and ICSI	41
FORM - E	Consent for Artificial Insemination or Intrauterine Insemination with Husband’s Semen / Sperm	42
FORM - F	Consent for Artificial Insemination or Intrauterine Insemination with Donor Semen	43
FORM - G	Consent for Freezing of Embryos	45
FORM - H	Consent for the Surgical Extraction of Sperm	47
FORM - I	Consent for Oocyte Retrieval / Embryo Transfer	48
FORM - J	Agreement for Surrogacy	50
FORM - K	Consent Form for the Donor of Oocytes	53
FORM - L	Consent Form for the Donor of Sperm	55
FORM - M	Information on Semen Donor	56

FORM – M1		
Information on Oocytes Donor		59
FORM – M2		
Information on Surrogate		62
FORM – N		
Results of screening of Semen Donors/Oocyte Donors/Surrogate Mothers		65
FORM - O		
Record of use of Donor Gametes and Surrogates		
A. For Donor Semen		66
B. For Oocyte Donors		68
C. For Surrogate Mother		69
Form - P		
Oocyte-Embryo Record		70
Form - Q		
Semen Analysis Report		72
FORM - R		
Contract between the ART Bank and the Semen Donor		73
FORM – R1		
Contract between the ART Bank and the Oocyte Donor		75
FORM - R2		
Contract between the ART Bank and the Surrogate		77
FORM - S		
Contract between the ART Bank and the Patient		79
FORM - T		
Contract between the ART Bank and the ART Clinic		81
FORM - U		
Contract between the Patient and the Surrogate		83
Form - V		
Oath of Secrecy		86

The Assisted Reproductive Technology (Regulation) Rules, 2010

1. Short Title and Commencement

- (1) These rules may be called the Assisted Reproductive Technology (Regulation) Rules, 2009.
- (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 1), 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, ART 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.
- (8) Whatever has been said for ART clinics above, or in the sections that follow, in regard to registration, shall also apply, as relevant, to ART banks and to research centres using human embryos.

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 ART 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 ART 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.

Other forms, where necessary, may be designed in accordance with the provisions of the existing related form(s) and these Rules, by the ART clinic, the ART bank or the State Board.

- (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

1.1 Primary (Level 1) Infertility Clinics

These would be clinics where preliminary investigations such as those mentioned below are carried out and type and cause of infertility diagnosed. They may carry out all types of infertility treatment that do not require handling of sperm, egg or embryo outside of the body. Such a primary infertility care unit or clinic 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 1 clinic or referred to a speciality (Level 2 or Level 3) clinic.

Examples of responsibilities of a Level 1 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 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 with drugs such as clomiphene citrate, with or without adjuncts like bromocriptine, eltroxin, dexamethasone or spironolactone.
- 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 1, 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.
- i) Conservative surgery either through a laparoscope or hysteroscope, or via laparotomy.

- j) Combined medical-surgical therapy by a co-ordinated team, for example in endometriosis.
- k) Assessment of follicular growth and ovulation by serial ultrasonography.

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

These clinics will not require registration.

1.2 Secondary (Level 2) Infertility Clinics

These clinics will require registration under the Act. They shall have facilities for artificial insemination using husband's semen (AIH), artificial insemination using donor semen (AID), and intrauterine insemination (IUI) using husband's or donor semen. They may 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 that Level 2 infertility clinics may have are mentioned in the following two sub-paras (1.1.1 and 1.1.2).

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) 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 (excepting on human embryos). Some examples of the first two functions are given below in sub-paras 1.2.1 to 1.2.3. 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, ART 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) Cryopreservation of gametes (patients' own) and embryos.

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 Andrologist, 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 or diploma 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 carrying out overseeing 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 or a surgeon with a post-graduate degree 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 three 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. Such persons would also be eligible to take a test to be designed and conducted by an appropriate designated authority.) 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.

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
- Liquid nitrogen storage tanks
- 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 accessible within a reasonable time.

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 histopathological 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 plastic ware 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 have been 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 ART bank inside the vagina or the cervix. 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 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 level 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 extracted sperm (MESA / PESA / TESA / TESE)

Microsurgical Epididymal Sperm Aspiration (MESA) 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 seminiferous tubules along with the sperm are recovered 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 21-35 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 hysterosalpingography). 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 ART 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 ART 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. Embryos can also be frozen using the vitrification technique.

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 risks 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, 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 - A1

(See Rules 10.1 and 14.1)

**FORM OF APPLICATION FOR REGISTRATION OR RENEWAL OF
REGISTRATION OF AN ART 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 ART 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 ART 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 ART 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 bank 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
..... (ART 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 - A2

(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 Research Centre on behalf of which I am making this application operates independently of – and is not a part of – any ART clinic or ART Bank.

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 & 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 (ART bank's no. _____; obtained from _____ ART 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:

Note: An appropriate modification of this form may be used for Artificial Insemination or Intrauterine Insemination of a single woman with donor semen.

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 them for research purposes; or (b) 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 handed over to my wife /
commissioning partner

Used for research purposes

Signed:

Dated:

***Wife / woman**

In the unforeseen event of my death, I would like the embryos

To perish

To be handed over to my husband /
commissioning partner

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 Surgical Extraction of Sperm
(See Rule 15.1)

Name of female partner
Name of male partner

We hereby request and give consent to the procedure of _____
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 fertilize 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)

Name(s) and address(es) of commissioning person(s) :

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 transfer in my _____ of
 1. _____ (no) of the oocytes mixed with the sperm
 2. _____ (no) of the resulting embryos
 3. _____ (no) of our cryo-preserved embryos
 4. _____ (no) of embryo(s) obtained anonymously
- e) the transfer of resulting embryos (number _____) into _____ who will act as my surrogate

(Tick the appropriate and strike off the others)

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

I/We consent that I/we shall be the legal parent(s) of the child and the child will have all the legal rights on me, in case of anonymous gamete / embryo donation.

I/We 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 Commissioning Person

Name, address and signature
of the Witness from the clinic

Name and signature of the Doctor

Consent of Husband / Partner (as and if applicable)

As the husband/partner, I consent to the course of the treatment outlined above. I understand that I will become the legal parent 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 surrogate mother for _____

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/anonymous donor.
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, or to ----- in case of death of both of them, or to ----- in case of guarantor of foreign couple or individual, as soon as I am permitted to do so by the hospital / clinic / nursing home where the child is delivered.

I have been provided with the written consent of all of those name(s) mentioned above.

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, under the provisions of the MTP Act; 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; and (b) I have not undergone blood transfusion in the last six months.

I also declare that I will not use drugs intravenously, or undergo blood transfusion excepting of blood obtained through a certified blood bank on medical advice.

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 Oocytes

(See Rule 15.1)

I, Ms. _____ consent to donate my eggs to couples / individuals 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.)

I understand and accept that 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.

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 and address of the donor _____

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 / individuals 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 ART 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 address of the donor _____

Name and signature of the Doctor

Name, address and signature
of the Witness from the ART bank

Name and address of the ART 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 - M1
Information on Oocyte 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 :
 - c. Donor
 - d. 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 - M2
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

DETAILED PHYSICAL EXAMINATION:

- 34. Pulse
 - 35. Blood pressure
 - 36. Temperature
 - 37. Respiratory system
 - 38. Cardiovascular system
 - 39. Per abdominal examination
 - 40. Per speculum examination
 - 41. Per vaginal examination
 - 42. Trans-vaginal sonography
 - 43. 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 ART bank :

Registration no.

A. For Semen Donors

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

B. For Oocyte Donors

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

C. For Surrogate mothers

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

The ART 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 ART 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		Day 1			Day 2			Day 3		Day 4	Day 5	Frozen Info.		
Date: Time: Sci.: Dr.:		Date:	Sci:		Date:	Sci.:		Date:	Sci.:	Date:	Sci.:	Date: Time:		
Hyal. Time: Inject Time:		Diss. Time: Score Time: Hrs.(from OPU):			Time: Hrs.:			Time: Hrs.:		Time: Hrs.:	Time: Hrs.:	Method: Slow / Vitri		
Egg	Comm.	PN	PB	Comm.	Cell#	Grade	Frag %	Cell#	Grade		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 Contd.
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)

ART 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 :	

Remark : Acceptable / Not acceptable	Biologist:
	Name:
	Signature:

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 ART bank and the Semen Donor
(See Rule 15.1)

The ART bank and the Donor agree to come into this contract today on the _____ day of _____ month, _____ (year), in _____ as per the following conditions.

First Part being _____ ART 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. _____ 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 ART 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 - R1

Contract between the ART bank and the Oocyte Donor
(See Rule 15.1)

The ART 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 _____ ART 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 ART 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 herself 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 accept 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 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 has been adequately counseled by the Bank about the procedure and its potential complications.
9. The Donor agrees not to discontinue treatment midway except on medical advice of the ART clinic.
10. 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.
11. The Donor agrees to accept the above amount and thereafter makes no other demands for the donation of oocyte by her.
12. 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.
13. 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 - R2

Contract between the ART bank and the Surrogate
(See Rule 15.1)

The ART 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 _____ ART 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 ART 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 permission 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

Witness 1

Second Part

Witness 2

Name, address and telephone number of the witnesses:

FORM - S

Contract between the ART bank and the Patient
(See Rule 15.1)

The ART 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 _____ ART 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 ART 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:

* Strike off what is not applicable

FORM - T

Contract between the ART bank and the ART Clinic
(See Rule 15.1)

The ART 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 _____ ART 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 ART 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:

- a. 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.
- b. 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.

- c. 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.
- d. 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
- e. The blood group and the Rh status of the individual shall be determined and placed on record by the Bank.
- f. 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.
- g. 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.
- h. The Clinic shall inform the bank about a successful clinical pregnancy and any successful birth that the Clinic comes to know of.
- i. The Clinic shall use any item obtained from the Bank only for the specific purpose for which it was obtained.
- j. The Bank or the Clinic shall not be responsible for the false report of any appropriately accredited laboratory for any specific tests.
- k. 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.
- l. 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 33 and 35 and Rule 15.1 (Form J) of the ART (Regulation) Act.

3. As per the provision of Section 33.3 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 33.2 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 5%, of the total amount, of Rs..... at the time of embryo transfer.

2nd instalment which will not be less than 5%, when she becomes pregnant.

3rd instalment of 5% at the end of first trimester.

4th instalment of 10% at the end of the second trimester.

5th instalment of 75% just after delivery.

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, in a similar fashion 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.

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

First Part (patient and spouse*)

Second Part (surrogate and spouse*)

Witness (1)

Witness (2)

Name, address and telephone number of the witnesses:

* if applicable

Form - V

Oath of Secrecy
(See rule 15.1)

I,, Chairman/Member of, or a member of the staff of ART clinic/ART 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:
.....
.....
.....

Signature of witness 1

Signature of witness 2

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

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THE ASSISTED REPRODUCTIVE TECHNOLOGY (REGULATION) BILL & RULES - 2009

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