F. No. U.11019/14/2022-HR
Government of India
Ministry of Health and Family Welfare
(Department of Health Research)

IRCS Building, Red Cross Road,
New Delhi, the 13th May, 2022.

To,

(1) Chief Secretaries of all States/Administrators of UTs
(2) Principal Secretaries/Secretaries of Health & Family Welfare Department of all State/UT Governments.

Subject:- Instructions based on proposed Assisted Reproductive Technology(Regulation) Rules, 2022 –reg.

Sir/Madam,

I am directed to say that Assisted Reproductive Technology(Regulation) Rules, 2022 and Surrogacy(Regulation) Rules, 2022 are yet to be notified for the purposes of The Assisted Reproductive Technology(Regulation) Act, 2021 and The Surrogacy(Regulation) Act, 2021.

2. A copy of the **Instructions based on proposed Assisted Reproductive Technology(Regulation) Rules, 2022** have been prepared and sent herewith as Annexure I in attachment.

3. All concerned authorities under State/UT Governments are required to take action on the applications [submitted as per Section 15 of The Assisted Reproductive Technology (Regulation) Act, 2021 and which are complete in all respect including deposit of registration fee] in accordance with Section 16 of The Assisted Reproductive Technology(Regulation) Act, 2021.

4. Till the time, The Assisted Reproductive Technology(Regulation) Rules, 2022 are notified, all State/UT Governments are requested to complete all preliminary action for scrutinizing the applications and inspection of the premises of clinics/banks by State/UT Board based on above referred **Instructions** within the stipulated time period as per Section 16(1) & 16(2) of The Assisted Reproductive Technology(Regulation) Act, 2021. However, the final orders either to grant registration or to reject the application as per Section 16(1) of The Assisted Reproductive Technology(Regulation) Act, 2021 may be issued only after Assisted Reproductive Technology(Regulation) Rules, 2022 are notified.

5. This issues with the approval of competent authority.

Yours faithfully,

(Dinesh Kumar)
Under Secretary to the Govt. of India
Tel. No.23736902

Annexure I

1. These may be called the Instructions based on the Assisted Reproductive Technology (Regulation) Rules, 2022.

2. Definitions.- Unless the context otherwise requires,-

(a) "Act" means the Assisted Reproductive Technology (Regulation) Act, 2021;

(b) "Collection" means the collection of sperms from Males without any surgical procedure;

(c) "Form" means a form appended to these rules;

(d) "Storage" means the procedure adopted for storage of gametes or embryos or ovarian tissues.

(2) The words and expressions used herein and not defined in these rules but defined in the Act, shall have the meanings, respectively assigned to them in the Act.

3. Assisted Reproductive Technology (ART) clinics and banks.- (1) These shall be two levels of clinics, namely:-

(i) Level 1 ART clinics, where only intrauterine insemination (IUI) procedure is carried out as part of treatment;

(ii) Level 2 ART clinics, where the procedures, or as the case may be, techniques, that attempt to obtain a pregnancy shall be carried out by any or all of the following, namely:-

(a) surgical retrieval of gametes;

(b) handling the oocyte outside the human body;

(c) use sperms for fertilization of oocytes;

(d) transfer of the embryo into the reproductive system of a woman;

(e) carryout storage of gametes or embryos or perform any kind of procedure or technique involving gametes or embryos.

Provided that such clinics may also undertake research.

(2). ART banks shall-

(i) be responsible for screening, collection and registration of the semen donor and cryopreservation of sperms;

(ii) perform screening and registration of oocyte donor;

(iii) operate as semen banks or oocyte banks or both;

(iv) maintain the records or data of all the donors and shall regularly update the National Registry as provided in sections 23, 27, 28 of the Act.

4. Staff requirement and qualifications in ART clinics and banks.- Staff requirement and their qualifications for two levels of ART clinics and banks shall be as specified in Part 1 of the Schedule.

5. List of minimum equipments.- The list of equipments are as specified in Part 2 of the Schedule.

6. Format for granting of licenses to clinics or banks.- The format for granting of licenses to clinics or banks shall be the same as that of certificate of registration granted under **para 8 below**.

7. Form and manner of an application for registration and fee payable thereof under sub-section (2) of section 15.- An application for registration shall be made by the ART clinics or any such health facility which are carrying out procedures related to the assisted reproductive technology, as defined in the Act, to the appropriate authority in Form-1 and by the ART banks in Form-2. Every application for registration shall be accompanied with a fee of: -

(i) Rupees **50,000** for Level 1 ART clinic;

(ii) Rupees **2,00,000** for Level 2 ART clinic;

(iii) Rupees **50,000** for ART bank:

Provided that if an application for registration of any ART clinic or ART bank has been rejected by the appropriate authority, no fee shall be required to be paid on re-submission of the application by the applicant for the same clinic and the application fees once paid shall not be refunded:

Provided further that the no fee shall be required to be paid by the establishments run by the institute under control of the Government.

8. Certificate of Registration.- The appropriate authority shall, after making such enquiry and after satisfying itself that the applicant has complied with all the requirements, shall grant a certificate of registration in Form 3 to the applicant. One copy of the certificate of registration shall be displayed by the registered ART clinic or ART bank at a conspicuous place at its place of business.

9. Manner of appeal.- The clinic or bank or the commissioning couple or the woman may prefer an appeal to the State Government or the Central Government under section 19 of the Act in the format as specified in Form 4.

10. The medical examination of donor.- The sperm or oocyte donor shall be tested for the following communicable diseases, namely:-

(a) Human immunodeficiency virus (HIV), types 1 and 2;

(b) Hepatitis B virus (HBV);

(c) Hepatitis C virus (HCV);

(d) Treponema pallidum (syphilis) through VDRL.

11. Grievance redressal.- Every clinic and every bank shall maintain a grievance cell in respect of matters relating to such clinics and banks and the manner of making a complaint before such grievance cell as specified in Form 5.

12. Insurance coverage/Guarantee for oocyte donor.- (i) The Intending couple or woman will purchase a general health insurance coverage in favor of oocyte donor for a period of 12 months from an insurance company or an agent recognized by the Insurance Regulatory and Development Authority established under the provisions of the Insurance Regulatory and Development Authority Act, 1999 for an amount which is sufficient enough to cover all expenses for all complications arising due to oocyte retrieval.

(ii) The intending couple shall sign an affidavit to be sworn before Metropolitan Magistrate or a Judicial Magistrate of first class giving guarantee as per the section 22 (4) (ii) of the Assisted Reproductive Technology (Regulation) Act, 2021.

13. Other duties of clinics.- (1) The ART clinic shall-

(a) ensure that all unused gametes or embryos shall be preserved by the assisted reproductive technology clinic for use on the same recipient and shall not be used for any other couple, or as the case may be, woman;

(b) allow cryopreservation of oocytes, sperms for onco-fertility patients undergoing treatment and for other such conditions, for duration longer than ten years with the permission from the National Board;

(c) ensure the controlled ovarian stimulation of woman in order to prevent ovarian hyperstimulation;

(d) ensure that pre-implantation genetic testing shall be used to screen the human embryos for known pre existing heritable or genetic diseases and when medically indicated;

(e) ensure that no pre-implantation genetic testing shall be done for sex selection for non-medical reasons or selection of particular traits due to personal preferences of the prospective parents or to alter or with a view to alter the genetic constitution of an embryo;

(f) maintain the following consent forms, namely;-

(i) consent form to be signed by the couple or woman as specified in Form 6;

(ii) consent for Intrauterine Insemination with husband's semen or sperm as specified in Form 7;

(iii) consent for Intrauterine Insemination with donor semen as specified in Form 8;

(iv) consent for freezing of embryos as specified in Form 9;

(v) consent for freezing gametes as specified in Form 10;

(vi) assent for freezing of gametes sperm or oocytes and parental consent as specified in Form 11;

(vii) consent for oocyte retrieval as specified in Form 12;

(viii) consent from oocyte donor as specified in Form 13.

(2) The ART banks shall maintain the following, namely:-

(i) record of use of donor gametes as specified in Forms 14, 14 A and 14B;

(ii) consent form for the donor of sperm as specified in Form 15.

14. Examination of gamete donors by ART banks.- The gamete donor shall be tested for the communicable diseases as specified in **para 10 above**.

15. Manner of obtaining information in respect of a sperm or oocyte donor by a bank.- The information about number of donors, both sperm and oocyte, screened, maintained and supplied to the clinics shall be maintained and be provided to the National Registry regularly.

16. Manner of obtaining the consent of the commissioning couple or individual for perishing or donating the gametes of a donor or embryo.- The consent of the commissioning couple or individual for perishing or donating the gametes of a donor or embryo shall be obtained in the format as specified in forms 9 and 10.

17. Research on human gametes or embryo within India.- (1) The research on human gamete or embryo within India shall be performed after obtaining consent of the commissioning couple for transfer of such gamete or embryo to identified empaneled research institute and notified by the National Board as specified in Forms 9 and 10.

(2) Subject to revision of the guidelines, the research under sub-rule (1) shall be permitted as per the Indian Council of Medical Research guidelines or Stem Cell research guidelines or the Bio-medical ethics guidelines.

18. Search and seizure of records.- Every ART clinic or bank shall allow inspection of

their place, equipment and records by the National Board, National Registry, State Board or appropriate authority or any officer authorized in this behalf. Such inspection of an already registered clinic may take place without any notice. The authorities on inspection shall ensure that entry and search procedure does not place at risk the gametes or embryos stored in the facility.

Schedule 1

Part 1

(see para 4 of the Instructions)

A. The staff requirements and qualifications of the staff in the ART clinics;

(a) ART Level 1 clinic: Minimum 01 gynecologist

Qualification: The gynecologist shall be a medical post-graduate in gynecology and obstetrics

(b) Staffing of ART Level 2 clinic: ART clinic Level 2 shall have a minimum of one gynecologist, one anesthetist, one embryologist and one counselor. The additional staff at the level of Director and Andrologist may be employed by the ART Level 2 clinics.

(c) Qualification of staff in ART Level 2 clinics shall be as under:

(i) Gyanecologist: The gynecologist will be a medical post-graduate in gynecology and obstetrics and should have record of performing 50 ovum pickup procedures under supervision of a trained ART specialist with at least three years of working experience in an ART clinic under supervision (In the case of gynecologists practicing ART or IVF and are working in ART clinics before the commencement of this Act a post graduate degree in gynecology and obstetrics with at least three years experience and record of 50 ovum pickup procedures shall be acceptable)

OR

A medical post-graduate in gynecology and obstetrics with super specialist Doctorate of Medicine or Fellowship in reproductive medicine with experience of not less than three years of working in an ART clinic.

(ii) Andrologist: The Andrologist in a clinic or a bank will be a Master of Chirurgiae or Diplomate of National Board in Urology with special training in Diagnosing and Treating Male infertility.

(iii) Embryologist: From the date of commencement of these rules, clinics will hire embryologists only with the following qualifications and experience, namely:-

Post-graduate in clinical embryology (graduated with full time program with minimum four semesters) from a recognised University with additional three years of human ART laboratory experiences in handling human gametes and embryos;

OR

Ph.D. holder full-time Ph.D. project shall be related to Clinical Embryology or assisted reproductive technology or fertility from a recognised university with an additional one year of human ART laboratory experience in handling human gametes and embryos;

OR
Medical graduate (MBBS) or Veterinary graduate (BVSc) with a post-graduate degree in Clinical Embryology (full-time program) from a recognised University with additional two years of ART laboratory experience in handling human gametes and embryos;

OR
Post-graduate in Life Sciences or Biotechnology with a minimum of one year of on-site, full-time clinical embryology certified training in addition to four years experience in handling human gametes and embryos in a registered ART level 2 clinic.

Note: As a one-time measure all embryologists working in ART or IVF clinics before the commencement of these rules, with the below mentioned qualifications and experience may be allowed to continue as an embryologist. However, after the commencement of these rules, all clinics will hire Embryologists with any of the above-mentioned qualification and experience as a criteria:-

Graduate in Life Sciences or Biotechnology or Reproductive Biology or Veterinary Science with at least five years experience of working in a registered ART or IVF clinic, who have performed at least 500 IVF lab procedures (including Intra Cytoplasmic Sperm Injection and at least 100 cycles of cryopreservation of embryos).

(iv) **Counsellor:** A person who is a graduate in Psychology or Clinical Psychology or Nursing or Life Sciences.

(v) **Anesthetist:** Anesthetist will be a medical post-graduate in Anesthesia.

(vi) **Director:** The director shall have a post-graduate degree in Medical or Life Sciences or Management Sciences.

B. **ART bank:** The ART bank shall have a minimum of one Registered Medical Practioner trained in the handling, preparation and storage of Semen samples.

Part 2
(See para 5 of the Instructions)

The minimum equipment in ART clinics and banks

(a) ART Level 1 clinics: (i) Microscope, (ii) Centrifuge, (iii) Refrigerator

(b) ART Level 2 clinics:

(a) Microscope;

(b) Incubator (minimum 02 in number);

(c) Laminar Airflow;

(d) Sperm counting Chambers;

(e) Centrifuge;

(f) Refrigerator;

(g) Equipment for cryopreservation;

(h) Ovum Aspiration Pump;

(i) USG machine with transvaginal probe and needle guard;

(j) Test tube warmer and

(k) Anesthesia resuscitation trolley.

(c) ART banks

(a) Centrifuge machine;

(b) Incubator;

(c) Microscope and

(d) Laminar Air Flow.

FORM 1

[See para 7 of the Instructions]

APPLICATION FORM

REGISTRATION FORM FOR ART CLINIC

Name of the ART clinic:

Address of the ART clinic:

City _____ State: _____ Pin Code: ☐☐☐☐☐☐

Tel. No (with STD Code) (ART clinic only):

Mobile No. (ART clinic):

E-mail:

Website if any:

1. Status of your ART clinic
   1. Government 2. Private
   3. Any other, please specify……

2. Date of establishment of your ART clinic ☐☐☐☐☐☐

3. Whether your ART clinic is registered under following Acts or Authorities (Please provide details) Y/N
   1. Medical Termination of Pregnancy (MTP) Act,
   2. Pre-Conception and Pre-Natal Diagnostic Techniques (PCPNDT) Act

4. Whether your ART clinic has Director
   1. Yes 2. No
   (a) Name
   (b) Qualification
   (c) Registration No. if applicable

5. Details of staff

Post.	Name.	Qualification.	Registration No. if applicable.
Gynaecologist			
Anaesthetist			
Clinical Embryologist			

Andrologist			
Counsellor			

6. List of equipments

7. Indicate which of the following ART procedures are being routinely carried out at your ART clinic

1. Yes 2. No

(a) Intra-uterine Insemination using Husband Semen (IUI-H);

(b) Intra-uterine Insemination using Donor Semen (IUI-D);

(c) *In vitro* Fertilization-Embryo Transfer (IVF-ET);

(d) Intra-cytoplasmic Sperm Injection (ICSI);

(e) Altruistic Surrogacy;

(f) Processing or storage of gametes (sperm & oocyte) and or embryos of patient;

(g) Pre-implantation Genetic Testing and

(h) Any other procedure, please specify…… .

8. Whether you have any facility for cryopreservation of patient sperm/oocyte and or embryo

1. Yes 2. No

9. If yes, then please provide the details

1. Yes 2. No

(a) Freezing of sperm;

(b) Freezing of oocytes;

(c) Freezing of zygotes;

(d) Freezing of embryos;

(e) Cryopreservation of ovarian tissue and

(f) Freezing of Testicular tissue.

10. Any additional Information

DECLARATION

I hereby declare that the entries in this form and the additional particulars, if any, furnished herewith are true to the best of my knowledge and belief.

Date: _____

FORM 2
[See para 7 of the Instructions]

APPLICATION FORM
REGISTRATION FORM FOR ART BANK

Name of the ART bank:

Address of ART bank:

City_____ State: _____ Pin Code:☐☐☐☐☐☐

Telephone No. (with STD Code) (ART bank only):

Mobile No. of (ART bank only):

E-mail:

Website:

1. Status of your ART bank
   1. Government 2. Private
   3. Any other, please specify……

2. Date of establishment of your ART bank ☐☐☐☐☐☐

3. Details of the Staff Available at your ART bank

Name.	Designation.	Qualification.

4. List of Equipments

5. Indicate which of the following procedures are being routinely carried out at your ART b
   1. Yes 2. No
   (a) Collection of Semen
      (i) Ejaculation;

(ii) Electroejaculation (in case of retrograde ejaculation).

(b) Processing of Sperm;
(c) Storage of Sperm and
(d) Provision /sourcing of oocyte donor.

6. Cryopreservation of sperm
1. Yes 2. No

7. Method of Freezing of sperm
1. Yes 2. No
(a) Sperm slow freezing;
(b) Sperm vitrification.

8. Whether Freezing of Testicular tissue
1. Yes 2. No

9. Any additional Information

DECLARATION

I hereby declare that the entries in this form and the additional particulars, if any, furnished herewith are true to the best of my knowledge and belief.

Date: _____

FORM 3
[See para 8 of the Instructions]

Certificate Of Registration
ART clinic (Level 1/Level 2) / ART bank
(To be issued in duplicate)

Certificate No.:……

1. In exercise of the powers conferred under Section 16 (1) of the Assisted Reproductive Technology (Regulation) Act, 2021, the Appropriate Authority …… …… hereby grants registration to the ART clinic named below for purposes of carrying out Assisted Reproductive Technology procedures as per the aforesaid Act, for a period of …….. ending on ……

   (a) Name and address of the ART clinic;

   (b) Type of institution (Government or Private) and

   (c) Type of facility: Level 1 or Level 2

   OR

   The ART bank named below for purposes of carrying out activities and procedures as per the aforesaid Act, for a period of …….. ending on ……

   (a) Name and address of the ART bank;

   (b) Type of institution (Government or Private).

2. This registration is granted subject to the aforesaid Act and Rules there under and any contravention there of shall result in suspension or cancellation of this certificate of registration before the expiry of the said period of five 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 Appropriate Authority

Date: ……
Place: ……

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 4
[See para 9 of the Instructions]

Appeal No./20……Made against ……..to the State Board or National Board

In the matter of:

Name and Address of Appellant
Versus
Name and Address of the Authority Whose Order is Challenged Respondent

Most respectfully showeth:

The above-mentioned appellant appeals against the order passed by the..... concerned Appropriate Authority at .....(Name of place and address) against the appellant in
(details of the case if any)

Dated.....

and sets forth the following grounds of objection of the order appealed: -

1. Particulars of the order including number of orders, if any, against which the appeal is Preferred.
2. Brief facts of the case.
3. Findings of the Appropriate Authority challenged.
4. Grounds of appeal.
5. Copy of the order enclosed along with all the documents relied upon by the Appellant.
6. Any other information/documents in support of appeal

Prayer:
That the appellant, therefore prays for the reasons stated above the order under the appeal be set aside and quashed and order deemed just and proper may kindly be passed in favor of the appellant.

Signature of the Appellant

Place: …….

List of Documents

S. No	Particulars	Page No.

FORM 5
[See para 11 of the Instructions]

Format for Making Complaint to Grievance Cell

Instructions. – (1) Please submit the complete form.

(2) Ensure all signatures are authorized and additional documentation is provided.

Patient Registering the Complaint

Name of the Patient:

Address line 1:

Address line 2:

City: Postal code:

Contact Number: Email:

I am the patient

In case of representation on behalf of the patient:

Name, Address and contact details of person other than patient making the complaint:

Date of Birth (DD-MM-YYYY):

Relationship to the Patient is

1. Legal Representative
2. Relative or Family member
3. Anonymous
4. Others

Status of the Patient 1. Alive 2. Deceased

Details of Complaint Filed Against (Respondent):

Name of the person or organisation:

Address line 1:

Address line 2:

City: Postal code:

Contact Number: Email:

Please describe your complaint in as much detail as possible. Be sure to include specific information the date, time, timelines of events and location of the incident(s), staff, and witness etc. Please enclose copies of any documents that you feel would be relevant to your case. Note: A copy of this complaint will be sent to the Respondent you have identified.

If needed, continue on separate sheet or files or documents. Check here if another sheet is attached.

Complainant's Signature

Date: ……..

FORM 6
[See para 13(e) (i) of the Instructions]

Consent Form to be Signed by the Couple or Woman

I/We have requested the clinic……..…… ……..……. (name and address of clinic) 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 for ovulation induction 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:
   (i) The oocytes will be retrieved in all cases.
   (ii) The oocytes will be fertilized.
   (iii) 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. I/ We fully consent to these procedures and to the administration of such drugs and anesthetics as may be necessary. We also consent to any other operative measures, which may be found to be necessary in the course of the treatment.
4. I/ We have been told of the risks of ultrasound directed follicle aspiration.
5. I/ We are aware that we are free to withdraw or vary the terms of this consent until the gametes and/ or embryos have been used in accordance with my/ our wishes. I am aware that this will have to be a written request
6. There is no certainty that a pregnancy will result from these procedures even in cases where good quality embryos are transferred.
7. If a clinical pregnancy does result from assisted conception treatment, I/ we understand there is an accepted risk of multiple pregnancy, an ectopic pregnancy or of a miscarriage. I/ We understand that as in natural conception, there is a small risk of fetal abnormality.
8. Medical and scientific staff can give no assurance that any pregnancy will result in the delivery of a normal living child.
9. The uncertainty of the outcome of the procedure has been fully explained to me/ us. I/ We fully understand the risks of treatment including;
   (i) it is not possible to guarantee that a follicle will develop in a given cycle and that

occasionally cycles have to be abandoned before egg retrieval.

(ii) there is a risk that spontaneous ovulation can happen prior to/or during the egg retrieval.

(iii) an egg is not always recovered from a follicle at the time of egg retrieval.

(iv) any eggs may be collected and fertilization of any collected eggs will occur

(v) is a risk that the cycle will be abandoned before Embryo Transfer if there is failure of fertilization, abnormal fertilization or failure of the embryo to cleave(divide)

(vi) a pregnancy may result from treatment.

(vii) treatment may be abandoned at any time if there are problems in the laboratory or with the culture system

10. I/ We have been fully informed of all that is involved with the IVF/ICSI technique and have been advised regarding the chances of success, the possibility of multiple pregnancy occurring and other possible complications of treatment by the doctor. I/ We have also received information relating to treatment by these techniques in order to assist us to become more fully aware of what is involved.

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.

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

Name and Signature of the couple (husband and wife) or Woman

Name, Address &Signature of the Witness from the clinic

Name and Signature of the Doctor

Name and Address of the ART clinic

Dated: ……

FORM 7
[See para 13(e) (ii) of the Instructions]

Consent for IUI /ICSI/IVF with Husband's Semen or Sperm

_____ and _____ _____, being husband and wife and both of legal age, authorize Dr._____ to inseminate the wife 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.

Signature of intending couple
Husband :
Wife:

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 8

[See para 13 (e) (iii) of the Instructions]

Consent for Intrauterine Insemination /ICSI/IVF with Donor Semen

I/We, ……. being of legal age, authorise Dr. …….. to inseminate me intrauterine with semen / sperm of a donor Aadhar no. …… (ART bank's no. ……; obtained from …… ART bank with valid registration no……..……) for achieving conception.

I/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.

I/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.

I/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). (if applicable)

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.

Signature of intending couple/ intending woman

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 9
[See para 13 (e) (iv) of the Instructions]

Consent for Freezing of Embryos

I/We, …… and ……., consent to freezing of the embryos that have resulted out of ART with sperm of …… and oocyte of ……... I/We understand that the embryos would be normally kept frozen for…… years. If we wish to extend this period, I/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) discard and destroy them off. I/ 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**

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

To perish ☐

Handed over to my wife ☐

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 /……(Specify name and details) ☐

Used for research purposes ☐

Signed: Dated:

Name, Address and Signature of the couple/woman

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

Name and Address of the ART clinic

Dated: ……..

*The appropriate option may be ticked
* Strike of which is not applicable

Terms and Conditions

1. Provision of Information

   As long as I have cryopreserved embryo in storage at clinic mentioned above, I hereby agree to contact the above clinic at least annually to provide current information indicating my address, telephone number, email address and contact details and intention regarding my cryopreserved embryos.

   Failure to:

   (i) contact the clinic for a period of twelve months;
   (ii) respond to a request for information from clinic within 90 days of receipt; shall constitute abandonment and signify my desire to terminate storage of Cryopreserved embryos.

   In the event of my failure to comply with (i) and (ii) above, I instruct the above-mentioned clinic and hereby consent to my Cryopreserved embryos either being destroyed and discarded or given for research

2. Payment of Fees

   I understand that I am responsible for the costs of cryopreservation and storage of my Cryopreserved embryos. Cryopreservation and storage fees are due and payable at the time of gamete cryopreservation, and at the beginning of each annual storage interval thereafter. I understand these fees are non-refundable and are not subject to prorated adjustment for partial storage intervals. Should the yearly fee for storage of my Cryopreserved embryos, remain unpaid for a period of one year after the first

invoice is forwarded to my address/email/informed to me telephonically the clinic can conclude that I am no longer interested in storing these specimen(s) and I hereby instruct the clinic to destroy of my Cryopreserved embryos or use for research.

3. Alternate Contact/Responsible Party

I hereby name ……, as an alternate contact and my representative to assume responsibility for sections 1 and 2 above in the event that I am unable due to illness. I have attached a signed acknowledgement by ……. that they have read this form and will be responsible for its provisions in the event that I cannot.

FORM 10
[See para 13 (e) (v) of the Instructions]

Consent for Freezing of Gametes/Sperm/Oocytes

I/We, …… and ……., consent to freezing of the my …….. (sperm/oocyte). We understand that the gametes would be normally kept frozen for ten years. In the exceptional circumstances If I/we wish to extend this period, we would let the ART clinic …….. (Name and address) 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) discard and destroy them off. We also understand that sometimes the quality of these …… sperm or occytes may decrease on subsequent thaw and that frozen gametes may have a lower pregnancy rate than when fresh gametes are transferred.

***Husband / Man**

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

To perish ☐

To be handed over to my wife/ ……..(specify name and details ☐

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/ ……(specify name and details) ☐

Used for research purposes ☐

Signed: Dated:
Name, Address and Signature of the couple/woman

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

Name and Address of the ART clinic

*The appropriate option may be ticked

Date: ……

Place: ……

Terms and Conditions

1. Provision of Information

   As long as I have cryopreserved embryo in storage at clinic mentioned above, I hereby agree to contact the above clinic at least annually to provide current information indicating my address, telephone number, email address and contact details and intention regarding my cryopreserved embryos.

   Failure to:

   (i) contact the clinic for a period of twelve months;
   (ii) respond to a request for information from clinic within 90 days of receipt; shall constitute abandonment and signify my desire to terminate storage of Cryopreserved embryos.

   In the event of my failure to comply with (i) and (ii) above, I instruct the above-mentioned clinic and hereby consent to my Cryopreserved embryos either being destroyed and discarded or given for research

2. Payment of Fees

I understand that I am responsible for the costs of cryopreservation and storage of my Cryopreserved embryos. Cryopreservation and storage fees are due and payable at the time of gamete cryopreservation, and at the beginning of each annual storage interval thereafter. I understand these fees are non-refundable and are not subject to prorated adjustment for partial storage intervals. Should the yearly fee for storage of my Cryopreserved embryos, remain unpaid for a period of one year after the first invoice is forwarded to my address/email/informed to me telephonically the clinic can conclude that I am no longer interested in storing these specimen(s) and I hereby instruct the clinic to destroy of my Cryopreserved embryos or use for research.

3. Alternate Contact/Responsible Party

I hereby name …… as an alternate contact and my representative to assume responsibility for sections 1 and 2 above in the event that I am unable due to illness. I have attached a signed acknowledgement by …… that they have read this form and will be responsible for its provisions in the event that I cannot.

FORM 11 (for minors)
[See para 13 (e) (vi) of the Instructions]

Assent for Freezing of Gametes
Sperm/Oocytes
and Parental consent

I …….. consent to freezing of my ……. (sperm/oocyte). I understand that the gametes would be normally kept frozen for ten years. In the exceptional circumstances If I/my parents/legal guardian wish to extend this period, I/ we would let the ART clinic**/**bank ……. (Name and address) 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) discard and destroy them off. I/ We also understand that sometimes the quality of these ……. sperm/occytes may decrease on subsequent thaw and that frozen gametes may have a lower pregnancy rate than when fresh gametes are used.

***Minor**

I authorize my parents / legal guardian to take the decision on my behalf.

Signed: Dated:

Undertaking by Parents / Legal Guardian

In the unforeseen event of my child's death, I would like the Gametes

To perish ☐

To be handed over to me/ my wife/ legal guardian ☐

Used for research purposes ☐

Signed: Dated:

Name , address signature of parents /child

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

Name and address of the ART clinic

*The appropriate option may be ticked

Date: ……..

Place: ……..

Terms and conditions

PARENTS'S /Legal Guardian's

1. Provision of Information

As long as I /we have cryopreserved gametes in storage at clinic mentioned above, I /We hereby agree to contact the above clinic at least annually to provide current information indicating my address, telephone number, email address and other contact details and intention regarding my cryopreserved gametes.

Failure to:

(i) contact …….. (name of clinic) for a period of twelve months;

(ii) respond to a request for information from clinic within 90 days of receipt;

(iii) provide a new address or forwarding address or email address where mail is returned to clinic as undelivered, shall constitute abandonment and signify my desire to terminate storage of Cryopreserved Gametes.

In the event of my failure to comply with (i), (ii) or (iii) above, I instruct the above-mentioned clinic and hereby consent to the destruction of my Cryopreserved gametes.

2. Payment of Fees

I /We understand that I am/We are responsible for the costs of cryopreservation and storage of my child's Cryopreserved Gametes. Cryopreservation and storage fees are due

and payable at the time of gamete cryopreservation, and at the beginning of each storage interval thereafter. I/We understand these fees are non-refundable and are not subject to prorated adjustment for partial storage intervals. Should the yearly fee for storage of my Cryopreserved Gametes remain unpaid for a period of one year after the first invoice is forwarded to my address/email address/ informed telephonically as it is listed in the clinical records at clinic can conclude that I /we agree to destroy my cryopreserved gametes or use them for research .

3. Failure to Provide Information or Pay Fees

In the event of my failure to clinic or to pay cryopreservation fees as set out in sections 1 and 2 above, I hereby consent to and instruct clinic to discard and destroy Cryopreserved Gametes as follows:
(i) to remove from storage for destruction (yes/no) ____ _____ _____
to be given for research purpose(yes/no)

4. Alternate Contact/Responsible Party
I /We hereby name _____, as an alternate contact and my representative to assume responsibility for sections 1 and 2 above in the event that I am unable due to illness. I have attached a signed acknowledgement by _____ that they have read this form and will be responsible for its provisions in the event that I cannot.

Contact details of alternate person
Name-
Address-
Phone Number-

FORM 12
[See para 13 (e) (vii) of the Instructions]

Consent for Oocyte Retrieval

Name(s) and address(es) of patient

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:

1. Being prepared for oocyte retrieval by the administration of hormones and other drugs

2. The removal of oocytes from my ovaries under ultrasound guidance / laparoscopy

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

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.

Signature of intending couple/ intending woman

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 woman

Name, address and signature
of the Witness from the clinic

Name and signature of the Doctor

Consent of Husband (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 13
[See para 13 (e) (viii) of the Instructions]

Consent Form for the Donor of Oocytes

I, Ms. ……., Address……. Mobile number……., AADHAR card number……. Willingly consent to donate my oocyte to couples / individuals who are unable to have a child by other means. At this stage and to the best of my knowledge I am free of any infectious diseases or genetic disorders

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.: If applicable)

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:

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

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.

Name, address and signature of woman

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.

Name, address and signature of the Witness from the clinic

Name and signature of the Doctor

Name and address of the ART clinic

Name and address of the ART bank that recruited and screened the donor

Date: ……

(This form will be filled by the ART clinic but a copy of the same has to be maintained by the ART bank in case the donor was recruited and screened by the bank)

FORM 14
[See para 13 (f) (i) of the Instructions]

Record of use of Donor Gametes

(A separate form to be used for each individual donor) AADHAR card no. to be entered

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

FORM 14 A
[See para 13 (f) (i) of the Instructions]

For Oocyte Donors AADHAR card no. to be entered (For donors recruited and screened by the ART bank)

Donor ID	Recruitment Date	Name of person Recruiting	Signature	Supply Date	ART clinic	Receipt attached (Yes / No)

Form 14B
[See para 13 (f) (i) of the Instructions]

Oocyte-Embryo Record (AADHAR card no. to be entered)

Patient name:
ID no.:

Day 0 Date: Time: Sci.: Dr.:		**Day 1** Date: Sci: Diss. Time: Score Time: Hrs.(from OPU):			**Day 2** Date: Sci.: Time: Hrs.:			**Day 3** Date: Sci.: Time: Hrs.:		**Day 4** Date: Sci.: Time: Hrs.:	**Day 5** Date: Sci.: Time: Hrs.:		**Frozen Info.** Date: Time:	
Hyal. Time: Inject Time:					Sci: Sci:								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 :

The ART bank will maintain a separate register which will give the name and address, telephone no. etc., of the donor, that will match with the donor 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 to maintain the above identity secret.

FORM 15
[See para 13 (f) (ii) of the Instructions]

Consent Form for the Donor of Sperm

I, Mr. …….. Address…….. Mobile number……. AADHAR card number……. Willingly consent to donate my sperm to couples / individuals who are unable to have a child by other means. At this stage and to the best of my knowledge I am free of any infectious diseases or genetic disorders

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: If applicable)

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

Signature of Donor

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.

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: …….