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Government of India
Ministry of Health and Family Welfare
(Department of Health Research)
Notification
New Delhi, the March 2022

G.S.R … (E) In exercise of the powers conferred by Section 42 of the Assisted Reproductive Technology (Regulation) ACT 2021, except as respects things done or omitted to be done before such supersession, the Central Government hereby makes the following rules namely:

1. Short Title and Commencement

1.1 These rules may be called the Assisted Reproductive Technology (Regulation) Rules, 2022.

1.2 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:

2.1 'act' means the Assisted Reproductive Technology (Regulation) Act,2021;

2.2 'form' means a form appended to these rules;

2.3 'section' means a section of the Act;

2.4 '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;

2.5 'ART' means Assisted Reproductive Technology;

2.6 'collection" means the collection of sperms from Males without any surgical procedure.

2.7 "storage" means the procedure adopted for storage of gametes or embryos or ovarian tissues

3. The other powers and functions of the National Board under clause (g) of section 5

3.1 The National Board shall, subject to provisions of this Act, rules and regulations made there under, take measures to develop new policies in the area of assisted reproductive technology and to assist the State Boards in accreditation, supervision and regulation of services of assisted reproductive technology clinics and banks in the country.

3.2 To encourage and promote training and research in the field of assisted reproduction.

3.3 To assist the central government in issuing guidelines, notifications and orders pertaining to Assisted Reproductive Technology.

3.4 Any other activities as directed by central government.

4. The other powers and functions of the State/UT Boards under clause (b) of sub-section (2) of Section 8

4.1 The State/UT Board shall, subject to provisions of this Act, rules and regulations made there under, shall assist the National Board to develop new policies in the area of assisted reproductive technology.

4.2 The State/UT Board shall supervise the accreditation and regulation of services of assisted reproductive technology clinics and banks in their respective states/UTs.

4.3 Any other activities as directed by central government.

5. Annual Report

The National /State Board shall prepare as per the prescribed format, its annual report, giving a full account of its activities during the previous financial year, and submit a copy to the Central / State Government.

6. Other functions of the National Registry under clause (d) of section 11

6.1 National Registry shall undertake analysis and management of the data provided to it as per the Act. The National Registry may involve other central government institute/s for the analysis and management of this data.

6.2 Any other activities as directed by central government/National Board.

7. Other functions of the Appropriate Authority under clause (h) of section 13.

7.1 In case required advisory committee may be constituted for addressing local issues related to ART clinics and banks.

7.2 Any other activities as directed by the Central Government, National Board, State Board.

8. Other powers of Appropriate Authority clause (d) of sub-section (1) of section 14.

8.1 Appropriate Authority will have the power to question any person involved in violation of the provisions of the Act and take necessary action as per section 14 of the Assisted Reproductive Technology (Regulation) Act, 2021.

8.2 Any other powers as delegated by the Central Government, National Board, State Board.

9. Code of conduct to be observed by Appropriate Authority

9.1 All Appropriate Authorities notified under the Act, inter-alia, shall observe the following code of conduct with respect to the Advisory Committee: -

9.1.1 ensure that a person who is the part of investigating machinery in cases under ART (Regulation) Rules, 2022, shall not be nominated or appointed as a member of the Advisory Committee;

9.1.2 ensure that no person shall participate as a member or a legal expert of the Advisory Committee if he or she has conflict of interest;

9.2 All Appropriate Authorities notified under the Act, inter-alia, shall observe the following code of conduct for processing complaints and investigations, namely: -

9.2.1 maintain appropriate diaries in support of registration of each of the complaint or case under the Act;

9.2.2 attend to all complaints and maintain transparency in the follow-up action of the complaints;

9.2.3 initiate investigation on each of the complaint within twenty-four hours of receipt of the complaint and complete the investigation within seven working days of receipt of such complaint.

9.3 All Appropriate Authorities notified under the Act, inter-alia, shall follow the following financial guidance, namely:

9.3.1 maintain a separate and independent bank account operated by two officers jointly;

10. ART Clinics and Banks

10.1 Levels of ART Clinics

10.1.1 Level 1 ART Clinic

These would be ART clinics where preliminary investigations are carried out including diagnosis of type, cause of infertility and only IUI is carried out as part of treatment.

10.1.2 Level 2 ART Clinic

These would be ART clinics where all/advanced investigations, diagnostic and therapeutic procedures in ART are carried out. Such clinics may also undertake research.

10.2 ART Banks

10.2.1 ART banks will be responsible for screening, collection and registration of the semen donor and cryopreservation of sperms.

10.2.2 The screening and registration of oocyte donor.

10.2.3 The ART banks may operate as Semen banks or oocyte banks or both.

10.2.4 ART Banks will maintain the records/data of all the donors and will regularly update the National Registry as per Section 23, 27, 28 of the Assisted Reproductive Technology (Regulation) Act, 2021.

11. Qualification of the employees in ART Clinics and Banks

Minimum requirement of staff and their qualification for the two levels of ART clinics and the ART Banks shall be as specified in Schedule I, Part-1.

12. The format for granting of licenses to the clinic or bank by the appropriate authority under sub-section (2) of section 14;

The format for granting license to ART clinics and banks is specified under Form 1 & 2.

13. The form and manner in which an application shall be made for registration and fee payable thereof under sub-section (2) of section 15;

An application for registration shall be made by the ART Clinics to the Appropriate Authority in duplicate, in Form 3 and by the ART Banks in Form 4. Every application for registration shall be accompanied by an application fee of: -

i) Rupees 1,00,000 for Level 1 ART Clinic

ii) Rupees 5,00,000 for Level 2 ART Clinic

iii) Rupees 1,00,000 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 body within 90 days of rejection:

PROVIDED FURTHER that any subsequent application shall be accompanied with the prescribed fee. Application fee once paid will not be refunded.

PROVIDED FURTHER that such establishments in the Government run institutes will not pay for application.

14. The facilities and equipment's to be provided and maintained by the clinics and banks under sub-section (4) of section 15.

14.1 Equipment in the ART clinics and Banks shall conform to the requirement as specified in Schedule 1, Part 2.

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

15. The conditions, form and fee for application of renewal of the registration of clinic or bank under section 17

15.1 An application for renewal of registration shall be made in duplicate in Form 3 & form 4, to the Appropriate Authority 60 days before the date of expiry of the certificate of registration.

15.2 The Appropriate 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 3 & form 4, for a further period of five years from the date of expiry of the certificate of registration earlier granted.

15.3 Every application for renewal of registration shall be accompanied by an application fee of: -

Rupees 1, 00,000 for Level 1 ART Clinic

Rupees 5, 00,000 for Level 2 ART Clinic

Rupees 1, 00,000 for ART Bank

15.4 If, after enquiry and after giving an opportunity of being heard to the applicant, the Appropriate Authority is satisfied that the applicant has not complied with the minimum requirement of the Act and these rules, 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 5 (ART Clinic) and 6 (ART Bank), within thirty days from the date of application for renewal.

15.5 In case of rejection, the applicant would have the right to appeal to the State Board against the decision of the Appropriate Authority, stating clearly the reasons for making the appeal, within 30 days of receiving the decision of the Appropriate Authority. The State Board should take a view on the appeal within 60 days of its receipt.

15.6 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 Appropriate Authority by the ART clinic and/or bank.

15.7 In case of failure of renewal of the registration, the clinics and or banks would be given time to complete the ongoing IVF procedures and continue maintenance of embryology lab till renewal is obtained up to 90 days, however new patient recruitment will not be allowed. If the renewal is not granted after 90 days, then

the ART clinic and or bank would transfer all the stored gametes to another registered ART clinic and or bank.

16 Certificate of Registration

16.1 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 duplicate, in Form 7 and Form 8 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

16.2 In case of any violation of the provisions of the Act If, after enquiry and after giving an opportunity of being heard to the applicant the Appropriate Authority is satisfied that the applicant has not complied with the requirements of the Act and these rules, it shall, for the reasons to be recorded in writing, reject the application for registration and communicate such rejection to the applicant as specified in 5 and 6.

16.3 In case of 16.2 above, the applicant would have the right to appeal to the State Board against the decision of the Appropriate Authority, stating clearly the reasons for making the appeal, within 30 days of receiving the decision of the Appropriate Authority. The State Board should take a view on the appeal within 60 days of its receipt.

16.4 The certificate of registration shall be non-transferable. In the event of change of ownership or change of management or on ceasing to function as ART clinic or ART bank, both copies of the certificate of registration shall be surrendered to the Appropriate Authority.

16.5 In the event of change of ownership or change of management of the ART Clinic or ART Bank the new owner or manager of such clinic or bank shall apply afresh for grant of certificate of registration.

17. The manner in which an appeal may be preferred to the State Government or the Central Government under section 19;

The format for appeal will be as specified in Form 9.

18. The criteria for availing the assisted reproductive technology procedures under clause (a) of section 21;

The criteria for availing the assisted reproductive technology procedures will be subject to the criteria mentioned under clause (j) of Section 2 of the Assisted Reproductive Technology (Regulation) Act 2021.

19. The medical examination of the diseases with respect to which the donor shall be tested under clause (b) of section 21.

Sperm/oocyte donor is tested for the following diseases:

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

19.2 Hepatitis B virus (HBV);

19.3 Hepatitis C virus (HCV);

19.4 Treponema pallidum (syphilis) through VDRL

19.5 Chlamydia

20. The manner of making a complaint before a grievance cell and the mechanism adopted by clinic under clause (f) of section 21.

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 compliant before such grievance cell shall be such as specified in Form 10.

21. The manner of providing information by the clinics and banks to the National Registry under clause (j) of section 21

All clinics and banks shall provide all information related to:

21.1 Enrolment of the commissioning couple, woman and gamete donors;

21.2 The procedures being undertaken; and

21.3 Outcome of the procedures, complications, if any, to the National Registry periodically.

22. The amount of insurance coverage for oocyte donor under clause (b) of Subsection (1) of section 22.

An insurance coverage of (amount)…….for a period of twelve months in favor of the oocyte donor by the commissioning couple or woman 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.

23. The manner of maintaining record by the clinics and banks under clause 9(a) of section 23.

23.1 Every ART Clinic and or Bank shall maintain a record of the names and addresses of the couple/woman who underwent ART procedure/tests, the names of their spouse or father and the date on which they first reported for such counseling, procedure or test.

23.2 All case related records, forms of consent, laboratory results, microscopic pictures, sonographic plates or slides, recommendations and letters shall be preserved by the ART Clinic/ Bank, for a period of ten years from the date of completion of ART procedures.

23.3 Every ART clinic/ bank shall send a complete report in respect of all ART

related procedures/techniques/tests conducted by them in respect of each month by5th day of the following month to the National Registry.

24. The manner of collection of gametes posthumously under clause (f) of Section 24.

The collection of sperms posthumously shall be done only if prior consent of the commissioning couple is available as specified in Form 11.

25. Other duties of the clinic under clause (h) of section 24.

25.1 Duties of ART Clinic

25.1.1 ART clinic shall ensure that all unused gametes /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/woman.

25.1.2 ART clinics shall allow cryopreservation of oocytes, sperms for onco-fertility patients undergoing treatment and for other such conditions, for duration longer than 10 years with permission from the National board.

25.1.3 Every ART clinic/ Bank shall intimate every change of employee, address and equipment installed, to the Appropriate Authority (at least thirty days in advance of the expected date of such change).

25.1.4 While retrieving oocytes, efforts should be made to retrieve not more than seven oocytes during one cycle from the donor. However, all formed follicles may be retrieved.

25.1.5 The Clinics shall ensure the controlled ovarian stimulation of woman in order to prevent ovarian hyperstimulation.

25.1 Consent forms to be maintained by the ART Clinics.

25.1.1 Consent Form to be signed by the Couple /woman as specified in Form 12.

25.1.2 Consent for Intrauterine Insemination with Husband’s Semen / Sperm as specified in Form 13.

25.1.3 Consent for Intrauterine Insemination with Donor Semen as specified in Form 14.

25.1.4 Consent for Freezing of Embryos as specified in Form 15.

25.1.5 Consent for freezing gametes as specified in Form 16.

25.1.6 Assent for Freezing of Gametes Sperm/Oocytes & Parental consent as specified in Form 17.

25.1.7 Consent for withdrawal as specified in Form 18.

25.1.8 Consent for oocyte retrieval as specified in Form 21.

25.1.9 Any other duties as directed by the central government/ National Board & State Board

25.2 Consent forms to be maintained by the ART Banks

25.2.1 Record of use of Donor Gametes as specified in Form 19, 19 A, 19 B.

25.2.2 Results of screening of Semen Donors / Oocyte Donor as specified in Form 20.

25.2.3 Consent Form for the Donor of Sperm as specified in Form 22.

25.2.4 Consent Form for the Donor of Oocytes as specified in Form 23.

26. The examination of donors by the assisted reproductive technology banks for diseases under clause (c) of sub section (2) of Section 27

Sperm/oocyte donor is tested for the following diseases:

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

26.2 Hepatitis B virus (HBV);

26.3 Hepatitis C virus (HCV);

26.4 Treponema pallidum (syphilis) through VDRL

26.5 Chlamydia

27. The manner of obtaining information in respect of a sperm or oocyte donor by a bank under sub section (6) of section 27.

Information about number of donors (sperm and oocyte), screened, maintained and supplied to the clinics shall be maintained and be provided to the National Registry regularly.

ART bank shall obtain all necessary information in respect of a sperm or oocyte donor as specified in Forms 24 A, 24 B.

28. The standards for the storage and handling of the gametes, human embryos in respect of their security, recording and identification under subsection (1) of section 28

28.1 Prior to the processing of patient gametes or embryos, intended for use in treatment or storage, the center must:

28.1.1 Carry out the following biological tests to assess the risk of cross contamination like HIV 1 and 2: Anti-HIV – 1, 2, Hepatitis B: HBsAg and Anti-HBc and Hepatitis C: Anti-HCV-Ab.

28.1.2 Semen culture shall be carried out on all semen samples before

preservation.

28.1.3 Devise a system of storage of gametes and embryos clearly separating: -

28.1.3.1 quarantined

28.1.3.2 unscreened

28.1.3.3 tested negative

28.1.3.4 tested positive

28.1.4 The center should have a separate storage facility of the gametes in case of HIV, Hepatitis, HCV and other such infected patients.

28.2 The center should ensure that the storage facilities for gametes and embryos:

28.2.1 are dedicated for the purpose, and adequate for the volume and types of activities

28.2.2 are designed to avoid proximity to ionizing radiation (radioactive material), any known potential source of infection and chemical/atmospheric contamination

28.2.3 have a storage-location system that minimizes the amount of handling required to retrieve gametes and embryos.

28.3 The center should also have procedures to deal with emergency situations that may cause damage to storage vessels, failure of storage conditions or both.

28.4 The center's documented procedures should also ensure that:

28.4.1 gametes and embryos are stored under controlled conditions that are validated and monitored.

28.4.2 gametes and embryos are packaged for storage in a way that prevents any adverse effects on the material and minimizes the risk of contamination.

28.4.3 records are kept indicating every occasion when gametes and embryos are handled during storage and release, and by whom.

28.4.4 records are kept indicating that gametes and embryos meet requirements for safety and quality before release.

28.5 The centers should store gametes and embryos in a designated area. Cryocans should be fitted with local alarms and be linked to an autodial or similar facility to alert staff to non-conformities outside normal working hours.

28.6 The center should have adequate staff and funding for an 'on-call' system for responding to alarms out of working hours, and adequate spare storage capacity

to enable transfer of samples when required.

28.7 All the centers having facility should have emergency back-up plan to handle these gametes / embryos in case of power failure/ fire breakout.

28.8 A center storing gametes and/or embryos for patients whose future fertility may be impaired by a medical condition or procedure should divide individual patients' samples into separate storage vessels.

28.9 Transfer of stored gametes and embryos from one ART clinic to another ART clinic can be permitted after permission from the National Board along with transfer of all records with appropriate consent and acceptance of both ART registered clinics.

28.10 Make arrangements for storage for duration longer than 10 years for cases of oncofertility under special circumstances where permission has to be taken from the National Board.

29. The manner of obtaining the consent of the commissioning couple or individual for perishing or donating the gametes of a donor or embryo under subsection (2) of section 28

The consent form is as specified in Form 15 & 16.

30. The manner of performing research on human Gametes or embryo within India under sub section (2) of section 30.

30.1 The couples should provide consent for transfer of embryo/gamete to identified empaneled research institute and notified by the national board. as specified in form 15 & 16.

30.2 Research is permitted as per ICMR guidelines/ stem cell research guidelines/ and biomedical ethics guidelines (subject to revision of the guidelines).

31. The manner of entry and search by the National Board, National Registry or the State Board or any officer authorized by it under sub section (1) of section 40.

Every ART Clinic / ART Bank shall allow inspection of the place, equipment and records to the National Board, National Registry, State Board or Appropriate Authority or any officer authorized in this behalf. Such an inspection of an already registered clinic may take place without any notice. It shall be ensured that entry and search procedure does not place at risk the gametes/ embryos stored in the facility.

32. Any other matter which is to be, or may be prescribed, or in respect of which provision is to be made under rules.

32.1 Public Information

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

32.1.2 The Appropriate Authority, the Central Government, the State Government, and the Government/Administration of the Union Territory may publish periodically lists of registered ART Clinics/Banks and findings from the reports and other information in their possession, for the information of the public and for use by the experts in the field while ensuring anonymity/ confidentiality of patients.

32.2 Meeting of the National/State Board

The Board shall meet at least once in six months and ensure that the quorum is maintained. The meeting may be conducted virtually or physically as per the instructions of the central government. The Board shall meet in place decided by the administrative ministry.

33. The board may co-opt the members for its meeting after approval of the central government for attending the proceedings of the said meeting

33.1 Any other functions/matter as directed by the Central Government.

Schedule 1 - Part 1

34. The staff requirements given below will be mandatory for all ART Clinics/Banks.

Level 1 ART Clinic - minimum staff requirement

01 Gynecologist with qualifications as specified below

01 Counselor with qualifications as specified below

Level 2 ART Clinic - minimum staff requirement

Director

02 Gynecologist with qualifications as specified below

02 Embryologist with qualifications as specified below (One Senior and one Junior Embryologist)

01 Andrologist with qualifications as specified below

01 Anesthetist with qualifications as specified below

01 Counselor with qualifications as specified below

ART Bank - minimum staff requirement

01 Registered Medical Practioner trained in preparation and storage of semen sample

01 Counselor

35. Qualifications

35.1 Gynecologist

35.1.1 The gynecologist will be a medical post-graduate in gynecology and obstetrics and should have record of preforming 50 oocyte retrievals under supervision of a trained ART specialist (Records of procedures to be maintained) OR with three years of training in a registered ART center OR with superspecialist DM /fellowship in reproductive medicine or experience of not less than 03 years in reproductive medicine.

35.1.2 Understanding of the causative factors of male and female infertility.

35.1.3 Knowledge of the practice and use of diagnostic methods for determining the cause of infertility.

35.1.4 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.

35.1.5 Competence in gynecological 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.

35.1.6 Must be knowledgeable about the principles of ovarian stimulation and the management of complications arising thereupon.

The responsibilities of the Gynecologist will include

i) Interviewing of the infertile couple initially.

ii) History taking.

iii) Physical examination of the female.

iv) Recommending appropriate tests to be carried out, interpreting them and treating medical disorders (such as infections and endocrine anomalies).

v) Carrying out gynecological endoscopy and ultrasonographic intervention for diagnosis and therapy of infertility.

vi) Carrying out ART procedure and other ancillary procedures as the case and facilities may warrant, based on diagnostic evidence.

vii) The ART specialist should do self-appraisal and maintain records for Audit.

35.2 Andrologist

35.2.1 The Andrologist in a clinic/ bank will be a urologist or a surgeon who has a post-graduate degree (MS General Surgery with training in Andrology that often takes on the task of treating male infertility along with some experience in the field of andrology or MCH/DNB Genitourinary surgery/Urology).

35.2.2 The additional experience includes:

35.2.2.1 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.

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

35.2.2.3 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.

35.2.2.4 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:

a) Recording case histories.

b) Prescribing appropriate diagnosis and treatment based on the diagnosis.

c) Carrying out such surgical procedures as warranted by the diagnosis.

d) Maintaining all the records, from the case history to the treatment given, and the patient consent forms.

e) Referring the couple to the Gynecologist for carrying out the appropriate ART procedure, if necessary, after the male factor has been duly investigated.

f) Referring the couple to the counsellor if necessary.

35.3 Senior Embryologist

35.3.1 Post graduate in clinical embryology (on site) / PhD holder (onsite) in clinical Embryology post-graduate degree(onsite) from a recognized university with additional one year of laboratory experiences of handling human Gametes and Embryos.

OR

Medical Graduate MBBS OR post graduate in life sciences/ clinical embryology/Biotechnology/Veterinary Sciences/Reproductive biology with minimal of 1 year on site clinical embryology certified training in addition to this have 2 years' experience of working in the Embryology lab of a registered ART level 2 clinic.

35.3.2 To ensure that all the necessary equipment's are present in the laboratory and are functional. He will be custodian of the laboratory and the functioning of the lab.

35.3.3 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 gynecologist.

35.3.4 To maintain records of all the procedures carried out in the laboratory.

35.4 Junior Embryologist

Graduate in Life sciences/ biotechnology/ reproductive biology/ veterinary science with three experiences in the relevant field OR Postgraduate in Life sciences/ biotechnology/ reproductive biology/ veterinary science.

35.5 Counsellor

35.5.1 A person who has at least a degree (preferably a post-graduate

degree) in Social Sciences, Social work, 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/Bank who is not engaged in any other full-time activity in the clinic can act as a counsellor.

35.5.2 The additional experience includes:

35.5.2.1 The counsellor must invariably apprise the couple of the advantages of adoption as against resorting to ART. An individual may act as a counsellor for more than one ART Clinic/Bank 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.

35.5.2.2 In ART Clinic/Banks carrying out pre-implantation genetic diagnosis or mitochondrial donation should ensure that patients have access to counsellors with appropriate knowledge and expertise in these specialisms, including a good understanding of the risks and implications for patients who have treatment involving mitochondrial donation techniques and any children that may be born following such treatment.

35.6 Anesthetist

Anesthetist should have a MD/ DA in anesthesia .The role of the anesthetist in a surrogacy clinic is to provide adequate comfort and pain relief to the patients during oocyte retrieval and embryo transfer procedures. The modality of the providing the same should depend on the patient cooperation. If the patient is comfortable, conscious sedation should be preferred. The ideal anesthetist technique should provide good surgical anesthetist with minimal side effects, a short recovery time, high rate of successful pregnancy, and shortest required duration of exposure. The key to anesthetist is to aim for pharmacological exposure of shortest duration with minimal penetration to follicular fluid anesthetist are also expected to have a broad general knowledge of all areas of medicine and surgery.

35.6.1 These include:

35.6.1.1 The management of airways and respiration.

35.6.1.2 The use of hemodynamic monitors to measure blood pressure.

35.6.1.3 The various methods of cardiovascular (heart) and pulmonary (lung) resuscitation should these organ systems suddenly fail

35.6.2 The role of the anaesthetist in IVF is to provide adequate comfort and pain relief to the patients during oocyte retrieval and embryo transfer procedures. The modality of the providing the same should depend on the patient cooperation. If the patient is comfortable, conscious sedation should be preferred. The ideal anaesthetic technique for IVF should provide good surgical anaesthesia with minimal side effects, a short recovery time, high rate of successful pregnancy, and shortest required duration of exposure. The key to anaesthesia is to aim for pharmacological exposure of shortest duration with minimal penetration to follicular fluid Anaesthesiologists are also expected to have a broad general knowledge of all areas of medicine and surgery.

35.6.3 There should be an anesthetic chart in the patient's notes, containing information such as:

35.6.3.1 Known drug allergies

35.6.3.2 Previous problems with an aesthetics or sedatives

35.6.3.3 Airway assessment

35.6.3.4 Whether the patient is taking any regular medication

35.6.3.5 Any post-operative instructions (e.g., whether the patient will need antibiotics).

35.6.4 The Clinics should ensure that their procedures are suitable for the type of anesthetic or sedative provided.

35.6.5 The Clinics should ensure that only an appropriately qualified person provides an anaesthetic. If an anaesthetic is used at remote sites clinics should have a resuscitation team led by an Advanced Life Support provider. Where this is not the case, the anaesthetists should provide competency-based evidence of their ability to provide both advanced life support and the safe transport of a patient requiring multi-system

35.7 Director

This should be a senior person who has had considerable experience in all

aspects of ART. The 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 adequately trained and 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 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 2

36. Requirement of Equipment and Facilities

36.1 ART Bank

36.1.1 A laboratory centrifuge

36.1.2 Laminar flow

36.1.3 Liquid nitrogen cans

36.1.4 Storage rooms and individual semen containers

36.1.5 A pharmaceutical refrigerator

36.1.6 Incubators

36.1.7 Microscope

36.1.8 Cryocans/ cryofreezers

36.1.9 Refrigerator

36.2 Level 1 ART Clinic

36.2.1 Centrifuge machine

36.2.2 Ultrasound machine

36.2.3 Laminar Air Flow

36.2.4 Binocular Microscope

36.2.5 Incubator

36.2.6 Semen wash processing facility

36.2.7 Refrigerator

36.3 Level 2 ART Clinic

36.3.1 Facility for control of temperature & humidity (Air handling unit)

36.3.2 Filtered air with an appropriate number of air exchanges per hour

36.3.3 Wall and floors are composed of materials that can be easily washed and Disinfected

36.3.4 A laminar flow bench with a thermostatically controlled heating plate

36.3.5 An IVF grade Stereo Microscope preferably with CCD camera and recording software

36.3.6 A routine high powered Trinocular light microscope (IVF grade and preferably with CCD camera and recording software)

36.3.7 A high-resolution inverted microscope with phase contrast or Hoffman Optics (with standard IVF grade objective), preferably with facilities for video recording

36.3.8 A micromanipulator

36.3.9 A CO2 incubator, preferably with a back up

36.3.10 A laboratory centrifuge

36.3.11 Equipment for freezing embryos

36.3.12 Liquid nitrogen cans for Screened Negative samples

36.3.13 Infected samples

36.3.14 A pharmaceutical refrigerator

36.3.15 Heating plates

36.3.16 Test tube heater

36.3.17 Heating blocks

36.3.18 Alloy blocks/ Plates

36.3.19 Biometrics (to restrict the entry)

36.3.20 Anaesthesia station and basic resusication equipment

36.3.21 VOC – Photoionisation detector

Part 3

37. Minimal Physical Requirements and Facilities for an ART Clinics and Banks

37.1 The clinics and banks should have facilities for reception, clinical and counselling activity, laboratory work, storage of confidential records, storing gametes and embryos, and staff.

37.2 The clinics and banks should display a copy of its Certificate of Registration where

it can easily be read by current and potential patients and donors.

37.3 The centre should ensure that its clinical facilities:

1. provide privacy and comfort for those:

    37.3.1.1 considering donation and seeking treatment

    37.3.1.2 undergoing examination and treatment, and

    37.3.1.3 producing semen specimens.

2. are equipped with backup and emergency clinical facilities that:

    37.3.2.1 are appropriate to the degree of risk involved in any planned procedure, and

    37.3.2.2 can cope with emergencies known to occur in this clinical field.

37.4 Counselling facilities

The clinics and banks should ensure that counselling facilities provide quiet and comfortable surroundings for private, confidential and uninterrupted sessions.

The clinics and banks should have on its premises laboratory services or outsource the laboratory services as required.

	Level 1 ART Clinic	**Level 2 ART Clinic**	**ART Bank**
General Requirements	1. Reception Area 2. Waiting Room 3. Consulting Room 4. Storage Space 5. Records Space 6. Examination Room with Privacy 7. Backup Power Supply 8. Fire Safety Arrangement	1. Reception Area 2. Waiting Room 3. Consulting Room 4. Storage Room 5. Records Room 6. Examination Room with Privacy 7. Fire Safety Arrangement	1. Reception Area 2. Waiting Room 3. Consulting Room 4. Storage Room 5. Records Room 6. Examination Room with Privacy 7. Backup Power Supply 8. Fire Safety Arrangement 9. Semen Collection Room
Laboratory Services	1. General purpose clinical laboratory (inhouse/ referral) 2. Blood Collection Area	1. General purpose clinical laboratory (inhouse/ referral) 2. Blood Collection Area	1. General purpose clinical laboratory (inhouse/ referral) 2. Blood Collection Area
Requirement for Clean Area	1. IUI Room 2. Semen Collection Room	1. IUI Room 2. Semen Collection Room	1. Semen Collection Room
Sterile Area	1. Autoclave Area 2. Semen Processing Laboratory 3. Autoclave Area	1. Semen Processing Laboratory 2. Operation Theatre 3. IVF/Culture Laboratory	1. Semen Processing and Freezing Laboratory 2. Storage Room for Cryopreserved

		4. Embryo Transfer Laboratory 5. Autoclaving Room	Semen/ Sperm

37.5 A well-designed ART clinic / ART banks 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.

37.5.1 Reception & Waiting area

37.5.2 Consulting Room/ Examination Room - 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.

37.5.3 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. 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 nontoxic. 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.

37.5.4 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.

37.5.5 IUI Room: There must be a separate area/room with an appropriate table for Intra-Uterine Insemination (IUI).

37.5.6 General purpose clinical laboratory (in house/referral) with a Blood Collection Area - This can be inhouse/ referral. The ART Clinic/Bank 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.

37.5.7 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.

37.5.8 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.

37.5.9 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. We should have laparotomy set with suture material. There has to be an emergency tie-up with nearby hospital in case of complications.

37.5.10 Embryo Transfer Room- 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. The Operation Theatre and embryo transfer room should be directly connected with the embryology laboratory complex.

37.5.11 The IVF/Culture 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:

i) A laminar flow bench with a thermostatically controlled heating plate
ii) A stereo microscopeA routine high-powered binocular light microscope
iii) A high-resolution inverted microscope with phase contrast or Hoffman optics, preferably with facilities for video recording
iv) A micromanipulator (if ICSI is done)
v) A CO2 incubator, preferably with a back up
vi) A hot air oven
vii) A laboratory centrifuge
viii) Equipment for freezing embryos
ix) Liquid nitrogen storage tanks
x) A refrigerator
xi) Appropriate steps need to be taken for the correct identification of gametes and embryos to avoid mix-ups. Preferably by using appropriate labelling system preferably with barcodes.
xii) 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.
xiii) 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.

37.5.12 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.

37.5.13 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.

37.5.14 Fireproof cabinets can be used maintaining records and fire safety arrangements.

37.5.15 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.

37.5.16 Maintenance & Quality Checks of the Laboratories: Each laboratory should 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 donor identity number should be clearly labeled on all the tubes, dishes and pipettes containing the gametes. All pipettes should be immediately discarded after use. Laminar flow hoods, 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 logbook should 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.

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

37.5.18 Back-up Facility- There should be no interruption in power supply to the incubator and to other essential services of the ART Bank. Given the power supply situation in India, it is, therefore, imperative that a power back up in the form of UPS systems and/or a captive power generation system is available in ART Bank.

FORM 1

License under the Assisted Reproductive Technology (Regulation) Act 2021

License No.: ……. Date: ……..

License is hereby granted to **Bank (Type)/ Clinic (Level)**

Name of the Director ART Clinic:

Address:

Under the Assisted Reproductive Technology (Regulation) Act, 2021 subject to the terms & conditions*

Last date of Application for Renewal:

Validity

Establishment Name:

Address:

Registration No.:

Date: …….

Place: …….

Signature & Seal

Appropriate Authority

Terms & Conditions

1. The License is not transferrable. The ART Clinic shall at all times be available for inspection by the Authorities
2. The licensee shall confirm such conditions as are prescribed in rule. for this type of facility.
3. The Licensee shall maintain proper medical record of the patients in case of birth or death the licensee shall give intimation to the local registrar of births and deaths.

FORM 2

License under the Assisted Reproductive Technology (Regulation) Act 2021

License No.: ……. Date: ……..

License is hereby granted to **Bank (Type)**

Name of the Director ART Bank:

Address:

Under the Assisted Reproductive Technology (Regulation) Act, 2021 subject to the terms & conditions.

Last date of Application for Renewal:

Validity

Establishment Name:

Address:

Registration No.:

Date: …….

Place: …….

Signature & Seal

Appropriate Authority

Terms & Conditions

1. The License is not transferrable. The ART Bank shall at all times be available for inspection by the Authorities.
2. The licensee shall confirm such conditions as are prescribed in rule. for this type of facility.
3. The Licensee shall maintain proper medical record of all donors
4. The Licensee shall send intimidation to the Licensing Authority about the closure or shifting of the facility.
5. It is obligatory on the part of licensee to inform the nearest police station in case of any suspicious activity or medico-legal cases.

FORM 3 (i)

Registration/ Renewal of Registration Form for Level 1 ART Clinic

Name of the ART Clinic: _____

Name of the Director of the ART Clinic/Hospital/Institution: _____

_____

Address of the ART Clinic: _____

_____

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

Tel. No (with STD Code) (ART Clinic only): _____

Mobile No. (ART Clinic/Hospital/Institution): _____

Fax No. (ART Clinic only): _____

E-mail: _____

Website: _____

1. Status of your ART Clinic
   1. Government 2. Semi-Government 3. Private
   4. Charitable Trust 5. NGO 6. Public Sector Undertaking
   7. Any other, please specify……..
2. Date of establishment of your ART Clinic ☐☐☐☐☐☐
3. Whether your ART Clinic is registered under PCPNDT Act
   1. Yes 2. No
4. If yes, then please give the details
   a. Registration number…… ……
   b. Date of registration ☐☐☐☐☐☐
5. Whether your ART clinic is within a hospital/Institution
   1. Yes 2. No

6. If yes, then please provide the Name and Address of the hospital/Institution

……

……

Details of the Staff Available at your ART Clinic

7. Whether your ART Clinic has a Director.

1. Yes 2. No

8. If yes, give the details of the qualification of Director

Qualification

Please indicate the highest qualification/degree

(1) Sl. No	(2) Name of the degree 1. Ph.D/DM/M.Ch. 2. PG/MD/MS/DNB	(3) Area/Discipline 1. Life Sciences 2. Medicine	(4) Experience (in yrs)
1	…….	……	☐☐

9. Whether your ART Clinic has a Gynecologist.

1. Yes 2. No

10. If yes, please indicate the total number of Gynecologists. ☐☐

11. Give the details of qualification of Gynecologist(s)

Qualification

Please indicate the highest qualification/degree

(1) Sl. No	(2) Name of the Degree 1. Fellowship/DM/M.Ch. 2. MD/MS/DNB 3. Diploma	(3) Area/Discipline 1. Obst. & Gynecology	(4) Experience in ART (in yrs)
1	……..….	…….……..	☐☐
2	……..….	…….……..	☐☐
3	……..….	…….……..	☐☐

Note: If more than three, then please add separate sheets accordingly.

12. Whether your ART Clinic has a Counselor

1. Yes 2. No

13. If yes, then please indicate the total number of Counselors ☐☐

14. Give the details of qualification of Counselor

Qualification

Please indicate the highest qualification/degree

(1) Sl. No	(2) Name of the Degree 1 Ph.D/DM/M.Ch. 2. PG Diploma 3. PG/MD/MS/DNB 4. Diploma 5. Graduate/MBBS	(3) Area/Discipline 1. Social Sciences 2. Psychology 3. Life Sciences 4. Medicine	(4) Experience (in yrs)
1	……..…	……..……..	☐☐
2	……..…	……..……..	☐☐
3	……..…	……..……..	☐☐

15. Number of paramedical staff members other than the specified above employed in your ART Clinic (Details of conservancy/ cleaning and maintenance staff is not required). ☐☐

16. Please provide the details of the other staff members in the table given below:

(1) Sl. No	(2) Name of the Post	(3) Qualification 1. Doctorate 2. Post Graduate 3. Graduate 4. Diploma 5. Under Graduate 6. Any other	(4) Area/Discipline 1. Medicine 2. Nursing 3. Life Sciences 4. Social Sciences 5. Psychology 6. Any other	(5) Duties
01	…….. .....……..…	…….. ……..…	…….. ……..	…… ……
02	…….. .....……..…	…….. ……..…	…….. ……..	…… ……
03	…….. .....……..…	…….. ……..…	…….. ……..	…… ……
04	…….. .....……..…	…….. ……..…	…….. ……..	…… ……

Infrastructure Facilities Available at Level 1 ART Clinic

17. Do you have in-house facility for processing semen?
    1. Yes 2. No

18. If no, whether outsourcing
    1. Yes 2. No

19. Does your Clinic have the following?
    1. Yes 2. No
    i) Reception Area
    ii) Waiting Room for Patients
    iii) Examination Room with Privacy
    iv) Storage Area
    v) Area for Maintaining Record
    vi) Autoclave Facility
    vii) Provision for Vermin Proofing
    viii) Semen Collection Room
    ix) Area for Changing into Sterile Garments
    x) Semen Processing Laboratory (as per GLP)
    xi) Clean Room for IUI
    xii) All and floors are composed of materials that can be easily washed and disinfected
    xiii) A Laminar Flow Bench
    xiv) A Stereo Microscope
    xv) A routine high powered binocular light microscope
    xvi) A Laboratory Centrifuge
    xvii) Liquid Nitrogen Storage Tanks
    xviii) A Refrigerator
    xix) Laminar Flow Hoods
    xx) Incubators
    xxi) Any other (Brief Description)

20. Appropriate steps taken for correct identification (name of the patient) of gametes.
    1. Yes 2. No

21. To avoid mixing of gametes whether proper labeling of patient's name is being done on
    1. Yes 2. No
    a) All tubes
    b) Dishes
    c) Pipettes

22. Whether your ART Clinic has got hormone assay facility

1. Yes 2. Outsource

23. Whether an appropriate provision for back-up power supply available at your Clinic?
    1. Yes 2. No

24. Indicate which of the following ART procedures are being routinely carried out at your ART Clinic
    1. Yes 2. No
    i) Artificial Insemination with Husband Semen (AIH)
    ii) Artificial Insemination with Donor Semen (AID)
    iii) Intra-uterine Insemination using Husband Semen (IUI-H)
    iv) Intra-uterine Insemination using Donor Semen (IUI-D)
    v) Processing or storage of gametes (sperm & oocyte) of patient
    vi) Any other procedure, please specify…….

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: _____

(Signature of the Director of the Level 1 ART Clinic)
Name: ……
Designation with Seal

FORM 3(ii)

Registration/ Renewal of Registration Form for Level 2 ART Clinic

SECTION- I (GENERAL INFORMATION)

Name of the ART Clinic: _____

Name of the Director of the ART Clinic/Hospital/Institution: _____

_____

Address of the ART Clinic: _____

_____

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

Tel. No (with STD Code) (ART Clinic only): _____

Mobile No. (ART Clinic/Hospital/Institution): _____

Fax No. (ART Clinic only): _____

E-mail: _____

Website: _____

1. Status of your ART Clinic
   1. Government 2. Semi-Government 3. Private
   4. Charitable Trust 5. NGO 6. Public Sector Undertaking
   7. Any other, please specify……

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

3. Whether your ART Clinic is registered under following Acts/Authorities (Please provide details)

(1)	(2)	(3)	(4)	(5)
S. No.	**Name of the authority**	**1. Yes 2. No**	**If yes, then please specify the Registration Number**	**Date of Reg. (DD-MM-YY)**
1	Medical Termination of Pregnancy (MTP) Act	☐	…….……....	☐☐☐☐☐☐

2	Pre-Conception and Pre-Natal Diagnostic Techniques (PCPNDT) Act	☐	.....	☐☐ ☐☐ ☐☐
3	Bio-Medical Waste (Management and Handling) Rules	☐	.....	☐☐ ☐☐ ☐☐
4	Clinical Establishment Act	☐	.....	☐☐ ☐☐ ☐☐
5	NOC from Fire Safety Department	☐	.....	☐☐ ☐☐ ☐☐

4. Whether your ART clinic is within a hospital/Institution
   1. Yes 2. No

5. If yes, then please provide the Name and Address of the hospital/Institution
   ……
   ……

6. Whether your hospital/Institution is having more than one ART clinics within the country
   1. Yes 2. No

7. If yes, then please indicate whether your ART clinic is
   1. Head Clinic 2. Sub-clinic/Branch

8. If head clinic, please specify total number of sub-clinics/branches under Head ☐☐ Clinic

9. Please give the name, address and contact details of the sub-clinics/branches which are situated in different regions of the country under the head clinic.
   ……
   ……
   ……

SECTION - II (MANPOWER)

Details of the Staff Available at your ART Clinic

10. Whether your ART Clinic/hospital has Director
    1. Yes 2. No

11. If yes, give the details of qualification of Director

Qualification

Please indicate the highest qualification/degree

(1) Sl. No.	(2) Name of the Degree 1. Ph.D./DM/M.Ch. 2. PG/MD/MS/DNB 3. PG Diploma 4. Diploma 5. Graduate/MBBS 6. Any other	(3) Area/Discipline 1. Medicine 2. Life Sciences 3. Any other	(4) Experience (in yrs)
1	……...	…….	☐☐

12. Whether your ART Clinic has a Gynecologist.
    1. Yes 2. No

13. If yes, please indicate the total number of Gynecologists. ☐☐

14. Give the details of qualification of Gynecologists.

Qualification

Please indicate the highest qualification/degree

(1) Sl. No.	(2) Name of the Degree 1. DM/M.Ch. 2. MD/MS/DNB 3. PG Diploma 4. Any other	(3) Area/Discipline 1. Obst. & Gynecology 2. Any other	(4) Experience in ART (in yrs)
1	……...	…….	☐☐
2	……...	…….	☐☐
3	……...	…….	☐☐

15. Whether your ART Clinic has Andrologist.
    1. Yes 2. No

16. If yes, then please indicate the total number of Andrologists ☐☐

17. Give the details of qualification of Andrologist.

Qualification

Please indicate the highest qualification/degree

(1) Sl. No.	(2) Name of the Degree 1. Ph.D./DM/M.Ch. 2. MD/MS/DNB 3. PG Diploma 4. Any other	(3) Area/Discipline 1. Urology 2. General Surgery 3. Any other	(4) Experience (in yrs)
1	……	…..……....	☐☐
2	……	…..……....	☐☐
3	……	…..……....	☐☐

Note: If more than three, then please add separate sheets accordingly.

18. Whether your ART Clinic has Clinical Embryologist.
    1. Yes 2. No

19. If yes, then please indicate the total number of Clinical Embryologists. ☐☐

20. Give the details of qualification of Clinical Embryologist.

Qualification

Please indicate the highest qualification/degree

(1) Sl. No.	(2) Name of the degree 1. Ph.D./DM/M.Ch. 2. PG/MD/MS/DNB/M.V.Sc. 3. PG Diploma 4. Diploma 5. MBBS/B.V.Sc./B.Sc. 6. Any other	(3) Area/Discipline 1. Medicine 2. Life Sciences 3. Veterinary Sciences 4. Any other	(4) Experience (in yrs)
1	…….……..	….....……..……..	☐☐
2	…….……..	….....……..……..	☐☐
3	…….……..	….....……..……..	☐☐

Note: If more than three, then please add separate sheets accordingly.

21. Whether your ART Clinic has Counselor
    1. Yes 2. No

22. If yes, then please indicate the total number of Counselors ☐☐

23. Give the details of qualification of Counselor

Qualification

Please indicate the highest qualification/degree

(1) Sl. No.	(2) Name of the Degree	(3) Area/Discipline	(4) Experience (in yrs)
	1. Ph.D./DM/M.Ch. 2. PG/MD/MS/DNB 3. PG Diploma 4. Diploma 5. Graduate/MBBS 6. Any other	1. Social Sciences 2. Psychology 3. Life Sciences 4. Medicine 5. Any other	
1	……	……	☐☐
2	……	……	☐☐

24. Whether your ART clinic has Anesthetist

1. Yes 2. No

25. If yes, then please indicate the total number of Anesthetist ☐☐

26. Give the details of qualification of Anesthetist

Qualification

Please indicate the highest qualification/degree

(1) Sl.	(2) Name of the Degree	(3) Area/Discipline	(4) Experience (in yrs)
	1. DM/M.Ch. 2. PG/MD/MS/DNB 3 P.G Diploma 4. Diploma 5 Graduate/MBBS 6. Any other	1. Anesthesiology 2. Any other	
1	……	……	☐☐
2	……	……	☐☐

27. Number of paramedical staff members other than the specified above employed ☐☐ in your ART Clinic.

28. Please provide the details of the other staff members (details of conservancy/ cleaning/ maintenance staff is not required) in the table given below:

(1) Sl. No	(2) Name of the Post	(3) Qualification 1. Doctorate 2. Post Graduate 3. Graduate 4. Diploma 5. Under Graduate 6. Any other	(4) Area/Discipline 1. Medicine 2. Nursing 3. Life Sciences 4. Social Sciences 5. Psychology 6. Any other	(5) Duties
0 1	…… ……..…	……..… ……..…	……..… ……...	…… ……
0 2	…… ……..…	……..… ……..…	……..… ……...	…… ……
0 3	…… ……..…	……..… ……..…	……..… ……...	…… ……
0 4	…… ……..…	……..… ……..…	……..… ……...	…… ……
0 5	…… ……..…	……..… ……..…	……..… ……...	…… ……

Note: Please add more sheets if more than 5

SECTION - III (INFRASTRUCTURE)

Infrastructure Facilities Available at ART Clinic

29. Does your ART clinic have the following?

1. Yes 2. No

i) Reception area
ii) Waiting room for patients
iii) Examination room with privacy
iv) A general-purpose clinical laboratory
v) Store room
vi) Record room
vii) Autoclave room

viii) Semen collection room
ix) Area for changing into sterile garments
x) Semen processing laboratory (as per GLP)
xi) Operation theatre well equipped for carrying out surgical endoscopy, transvaginal ovum pick-up, embryo transfer and should be equipped for emergency resuscitative procedures
xii) Embryology laboratory complex
xiii) Operating table for carrying out the procedures
xiv) Whether the sterile area is air conditioned with fresh air filtered through an appropriate filter system along with ambient temperature of 22^{o}c – 25^{o}c (air handling unit)
xv) Pre and post operation areas
xvi) Bio medical waste disposal system
xvii) Toilet room for the patients-
xviii) Lift facility
xix) Fire exit area

30. Whether Embryology Laboratory Complex is provided with following-
1. Yes 2. No

i) Facility for control of temperature & humidity (Air handling unit)
ii) Filtered air with an appropriate number of air exchanges per hour
iii) Wall and floors are composed of materials that can be easily washed and Disinfected
iv) A laminar flow bench with a thermostatically controlled heating plate
v) An IVF grade Stereo Microscope preferably with CCD camera and recording software
vi) A routine high powered Trinocular light microscope (IVF grade and preferably with CCD camera and recording software)
vii) A high-resolution inverted microscope with phase contrast or Hoffman Optics (with standard IVF grade objective), preferably with facilities for video recording
viii) A micromanipulator (if ICSI is done)
ix) A CO_2 incubator, preferably with a back up
x) A hot air oven
xi) A laboratory centrifuges
xii) Equipment for freezing embryos
xiii) Liquid nitrogen cans for
a) IVF
b) Infected samples
xiv) A pharmaceutical refrigerator
xv) Heating plates
xvi) Test tube heater

xvii) Heating blocks
xviii) Alloy blocks/ Plates
xix) Biometrics (to restrict the entry)
xx) Temperature
xxi) CO_2 analyzer
xxii) Volatile Organic Compounds (VOCs) Filtration system
xxiii) IVF Software
xxiv) Ovum Pick-Up (OPU) Pump
xxv) CCD Monitoring System
xxvi) IVF Witness System
xxvii) Auto-analyzer for Sperm Function Test
xxviii) Computer Assisted Semen Analysis (CASA)
xxix) CO_2 and Triple gas Manifold
xxx) Makler Chamber
xxxi) Cryofreezer
xxxii) Any other (Brief Description)
xxxiii) Whether you have separate incubators for
  a) Oocytes
  b) Sperms
xxxiv) To avoid mixing of gametes or embryos whether proper labeling of patient's name is being done on
  i) All tubes
  ii) Dishes
  iii) Transfer pipettes
xxxv) Whether all used pipettes are immediately discarded

31. Whether your ART Clinic has got hormone assay facility?
  1. Inhouse 2. Outsourced

32. Do you have Microbiology Lab?
  1. Inhouse 2. Outsourced

33. Do you have Clinical Chemistry Laboratory?
  1. Inhouse 2. Outsourced

34. Do you have facility for carrying out Histopathological Studies?
  1. Inhouse 2. Outsourced

35. Whether an appropriate provision for back-up power supply available at our ART clinic?
  1. Yes 2. No

SECTION - IV (PROCEDURES)

36. Indicate which of the following ART procedures are being routinely carried out at your ART Clinic

		1. Yes	2. No
i)	Artificial Insemination with Husband Semen (AIH)		
ii)	Artificial Insemination with Donor Semen (AID)		
iii)	Intra-uterine Insemination using Husband Semen (IUI-H)		
iv)	Intra-uterine Insemination using Donor Semen (IUI-D)		
v)	*In vitro* Fertilization-Embryo Transfer (IVF-ET)		
vi)	Gamete Intrafallopian Tube Transfer (GIFT)		
vii)	Intra-cytoplasmic Sperm Injection (ICSI)		
viii)	Physiological Intra-cytoplasmicSperm Injection (PICSI)		
ix)	Intra-cytoplasmic Morphologically Selected Sperm Injection (IMSI)		
x)	Round Spermatid Nucleus Injection (ROSNI)		
xi)	Elongated Spermatid Injection (ELSI)		
xii)	Percutaneous Epididymal Sperm Aspiration (PESA)		
xiii)	Microsurgical Epididymal Sperm Aspiration (MESA)		
xiv)	Testicular Sperm Aspiration (TESA)		
xv)	Testicular Sperm Extraction (TESE)		
xvi)	Processing or storage of gametes (sperm & oocyte) and or embryos of patient		
xvii)	Pre-implantation Genetic Diagnosis (PGD)		
xviii)	Pre-implantation Genetic Screening (PGS)		
xix)	Endometrial Receptivity Array		
xx)	Time Lapse Imaging		
xxi)	Any other procedure, please specify……		

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

1. Yes 2. No

38. If yes, then please provide the details

		1. Yes	2. No
i)	Freezing of sperm		
ii)	Freezing of oocytes		
iii)	Freezing of zygotes		
iv)	Freezing of embryos		
v)	Cryopreservation of ovarian tissue		
vi)	Freezing of Testicular tissue.		

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: _____

(Signature of Director of the ART Clinic/Hospital/Institute)

Name: …….

Designation with Seal: ……

FORM 4

Registration/ Renewal of Registration Form for ART Bank

SECTION- I (GENERAL INFORMATION)

Please follow the instructions given in the Instruction Manual while filling the proforma and use capital letters only.

Name of the ART Bank: _____

Name of the Director of ART Bank: _____

Address of ART Bank: _____

_____

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

Telephone No. (with STD Code) (ART Bank only): _____

Mobile No. of Director (ART Bank only): _____

Fax No. (ART Bank only): _____

E-mail: _____

Website: _____

1. Status of your ART Bank
   1. Government 2. Semi-Government 3. Private
   4. Charitable Trust 5. NGO 6. Public Sector Undertaking
   7. Any other, please specify……

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

3. Whether your ART Bank is registered under following Acts/Authorities (Please provide details)

(1)	(2)	(3)	(4)	(5)
S. No.	**Name of the authority**	**1. Yes 2. No**	**If yes, then please specify the Registration Number**	**Date of Reg. (DD-MM-YY)**
1	Bio-Medical Waste (Management and Handling) Rules	☐	……..	☐☐ ☐☐ ☐☐
2	NOC from Fire Safety Department	☐	……..	☐☐ ☐☐ ☐☐

4. Whether your ART Bank is within a hospital/Institution
   1. Yes 2. No

5. If yes, then please provide the Name and Address of the hospital/Institution
   ……
   ……

6. Whether your Bank is having more than one ART Bank within the country
   1. Yes 2. No

7. If yes, then please indicate whether your ART Bank is
   1. Head Branch 2. Sub-Branch

8. If head Branch, please specify total number of sub-branches under head branch-☐☐

SECTION - II (MANPOWER)

Details of the Staff Available at your ART Bank

9. Whether your ART Bank has Director.
   1. Yes 2. No

10. If yes, give the details of qualification of Director

Qualification

Please indicate the highest qualification/degree

(1) Sl. No.	(2) Name of the Degree 1. Ph.D./DM/M.Ch. 2. PG/MD/MS/DNB 3. PG Diploma 4. Diploma 5. Graduate/MBBS 6. Any other	(3) Area/Discipline 1. Medicine 2. Life Sciences 3. Hospital administration 4. management 5. Any other	(4) Experience (in yrs)
1	……..	..…….	☐☐

11. Give the details of all other medical staff employed in your bank with names and indicate the highest qualification/ degree of each staff.

(1) Sl. No.	(2) Name of the degree 1. Ph.D./DM/M.Ch. 2. MD/MS/DNB 3. MBBS 4. PG Diploma/Degree 5. Any other	(3) Area/Discipline 1. Urology 2. General Surgery 3. Life Sciences 4. Other	(4) Duties/ Responsibility in brief	(5) Experience (in yrs)
1	…….	……..….	…….	☐☐
2	…….	……..….	…….	☐☐
3	…….	……..….	…….	☐☐
4	…….	……..….	…….	☐☐
5	…….	……..….	…….	☐☐
6	…….	……..….	…….	☐☐
7	…….	……..….	…….	☐☐

12. Whether your ART Bank has Counselor
    1. Yes 2. No

13. If yes, then please indicate the total number of Counselors ☐☐

14. Give the details of qualification of Counselor

Qualification

Please indicate the highest qualification/degree

(1) Sl. No.	(2) Name of the Degree 1. Ph.D./DM/M.Ch. 2. PG/MD/MS/DNB 3. PG Diploma 4. Diploma 5. Graduate/MBBS 6. Any other	(3) Area/Discipline 1. Social Sciences 2. Psychology 3. Life Sciences 4. Medicine 5. Any other	(4) Experience (in yrs)
1	……..……	……..…	☐☐
2	……..……	……..…	☐☐
3	……..……	……..…	☐☐

15. Number of paramedical staff members other than the specified above employed in your ART Bank (Details of conservancy/cleaning staff is not to be entered) ☐☐

16. Please provide the details of the other paramedical staff members in the table given below:

(1) Sl. No	(2) Name of the Post	(3) Qualification 1. Doctorate 2. Post Graduate 3. Graduate 4. Diploma 5. Under Graduate 6. Any other	(4) Area/Discipline 1. Medicine 2. Nursing 3. Life Sciences 4. Social Sciences 5. Psychology 6. Any other	(5) Duties
01	…… ……	…… ……	…… ……	…… ……
02	…… ……	…… ……	…… ……	…… ……
03	…… ……	…… ……	…… ……	…… ……
04	…… ……	…… ……	…… ……	…… ……

(**Note**: If more than 4, then please add separate sheets accordingly.)

SECTION - III (INFRASTRUCTURE)

Infrastructure Facilities Available at ART Bank

17. Does your ART Bank have the following?

1. Yes 2. No

i) Reception Area
ii) Waiting Room
iii) Examination Room with Privacy
iv) Store Room
v) Record Room
vi) Autoclave Room
vii) Semen Collection Room
viii) Separate Room for Counseling
ix) Bio-medical Waste Disposal System
x) Toilet Room for the Patients
xi) Fire exit area
xii) Area for changing into sterile garments
xiii) Semen processing laboratory (as per GLP)

18. Whether your laboratory is equipped with

1. Yes 2. No

i) A laboratory centrifuges
ii) Laminar flow
iii) Liquid nitrogen cans
iv) storage rooms and individual semen containers
v) A pharmaceutical refrigerator
vi) Incubators
vii) Cryofreezer
viii) Any other (Brief description)……..

19. To avoid mixing of the samples whether proper labeling of donor name is being done on

1. Yes 2. No

i) All tubes
ii) Dishes
iii) Transfer pipettes

20. Whether an appropriate provision for back-up power supply available at your ART Bank

1. Yes 2. No

21. Screening of Sperm donor/oocyte donors/patient for communicable and sexually transmitted diseases is being done?

1. Yes 2. No

22. Whether provisions of Semen collection, Processing and analysis available?
    1. Yes 2. No

23. Whether Basic Semen analysis done as per WHO?
    1. Yes 2. No

24. Provisions for Advanced (Sperm Function Test)?
    1. Yes 2. No

SECTION - IV PROCEDURES

25. Indicate which of the following procedures are being routinely carried out at your ART Bank
    1. Yes 2. No
    i) Collection of Semen
        a) Ejaculation
        b) Electroejaculation (in case of retrograde ejaculation)
    ii) Processing of Sperm
    iii) Storage of Sperm
    iv) Provision /sourcing of oocyte donor

26. Cryopreservation of sperm
    1. Yes 2. No

27. Method of Freezing of sperm
    1. Yes 2. No
    i) Sperm slow freezing
    ii) Sperm vitrification

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

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: _____

(Signature of Director of the ART Bank)

Name: …….

Designation with Seal: …….

FORM 5

No……

Rejection of Application for Registration or Renewal of Registration
ART Clinic (Level 1/ Level 2)

In exercise of powers conferred under Section 19 of the Assisted Reproductive Technology (Regulation) Act 2021, 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 Appropriate Authority

Date: ……

SEAL

*strike out whichever is not applicable or necessary

FORM 6

Rejection of Application for Registration
or
Renewal of Registration
ART Bank (Semen/Oocyte/Both)

In exercise of powers conferred under Section 19 of the Assisted Reproductive Technology (Regulation) Act 2021, the Appropriate Authority hereby rejects the application for grant*/ renewal* of registration of the ART Bank named below for the reasons stated.

Name and address of the ART Bank:

Name of applicant who has applied for registration:

Reasons for rejection of application for registration:

Signature, Name and Designation
of the Appropriate Authority

Date: ……

SEAL

***strike out whichever is not applicable or necessary**

FORM 6
Certificate Of Registration
ART Clinic (Level 1/Level 2)
(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) Name of applicant for registration
   c) Name of Director of the ART Clinic:
   d) Type of institution (Govt. / Private)
   e) Type of facility: Level 1 / Level 2

2. This registration is granted subject to the aforesaid Act and Rules there under and any contravention thereof 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 7
Certificate of Registration
ART Bank (Semen/Oocyte/Both)

(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 BANK named below for purposes of carrying out Assisted Reproductive Technology procedures as per the aforesaid Act, for a period of …….years ending on ……...
   a) Name and address of the ART Bank:
   b) Name of applicant for registration
   c) Name of Director of the ART Bank:
   d) Type of institution (Govt. / Private)

2. This registration is granted subject to the aforesaid Act and Rules there under and any contravention thereof shall result in suspension or cancellation of this certificate of registration before the expiry of the said period of ……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 7
Certificate of Registration
ART Clinic (Level 1/Level 2)
(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 ……..years ending on ……..
   a) Name and address of the ART Clinic:
   b) Name of applicant for registration
   c) Name of Director of the ART Clinic:
   d) Type of institution (Govt. / Private)
   e) Type of facility: Level 1 / Level 2

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

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 8
Certificate of Registration
ART Bank (Semen/Oocyte/Both)

(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 BANK named below for purposes of carrying out Assisted Reproductive Technology procedures as per the aforesaid Act, for a period of ……..years ending on ……
   a) Name and address of the ART Bank:
   b) Name of applicant for registration
   c) Name of Director of the ART Bank:
   d) Type of institution (Govt. / Private)

2. This registration is granted subject to the aforesaid Act and Rules there under and any contravention thereof shall result in suspension or cancellation of this certificate of registration before the expiry of the said period of …….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 9
Before the Central Appellate Authority
Or the State Appellate Authority
Appeal No./20……..……

In the matter of:

Name and Address of Appellant (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: -

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

Prayer.
That the appellant, therefore prays for the reasons stated above and as may be argued at the time of hearing, the records and proceedings be called for, this appeal be allowed, 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: ……..
Date: ……..

Verification

I, ... do hereby verify that the contents of para ……..……to ……..... are true and correct to the best of my knowledge and belief and no part is false and nothing material has been concealed therein.

Signature of the Appellant

FORM 9(i)

[Refer rule …….]

Proforma/ Affidavit before the Central Appellate Authority Orthe State Appellate Authority

In the matter of:

Name of the Appellant (Appellant)

Versus

Concerned Appropriate Authority (Respondent)

AFFIDAVIT

I..... S/o or D/o…… ……aged..... R/o..... .... do hereby solemnly declare as under:

37.2 That I am the Appellant in the captioned matter filed before the Appellate Authority and aware of all the facts and circumstances of the case, hence competent to swear this affidavit.

37.3 That the accompanying Memo of Appeal has been drafted by my counsel under my instruction and the same has been understood by me, the same may be read as the part and parcel of this affidavit, and the same has not been repeated here for the sake of brevity.

Deponent

Verification

Verified on this day ..... of ……..... (month and year) that the contents of the appeal are true and correct on the basis of my knowledge/records/documents/ legal advice received from the counsel and nothing material has been concealed therefrom.

Deponent

FORM 9 (ii)
APPENDIX No…
See Rule …….

Before the Central Appellate Authority or the State Appellate Authority

In the matter of:

Name of the Appellant (Appellant)
Versus
Concerned Appropriate Authority (Respondent)

Index

S. No	Particulars	Page No.

Signature of the Appellant

SYNOPSIS

S. No	Date	Particular of Events

Signature of the Appellant

List of Documents

S. No	Particulars	Page No.

FORM- 10

Format for Making Complaint to Appropriate Authority Against an ART Clinic (Level 1/Level 2) / ART Bank (Semen/Oocyte/Both)

Instructions

37.3.1.1 Please submit the complete form
37.3.1.2 Ensure all signatures are authorized and additional documentation is provided
37.3.1.3 Submit the completed form to the Appropriate Authority

The Appropriate Authority reviews all complaints and all complaints are treated in the same manner and assessed through the same review process. All complaints are reviewed in the order they are received. Please be aware that the review process is detailed and can be lengthy, depending on the circumstances. The length of time required for resolution will also vary. Once the Authority has received your complaint, you will be notified through mail.

Person Registering the Complaint
Name of the Person

Address line 1:

Address line 2:

City: Postal code:

Contact Number: Email:

I am the patient

I am representing the patient for the purposes of this complaint and I have completed the Authorization for Representation form.

Date of Birth (DD-MM-YYYY):
Relationship to the Patient is
1. Patient (Self)
2. Legal Representative
3. Relative /Family member
4. Anonymous
5. Others

Patient Information (If Different from Above)

Name:

Address line 1:

Address line 2:

City: Postal code:

Contact Number: Email:

Date of Birth (DD-MM-YYYY):

Status of the Patient 1. Alive 2. Deceased

Subject of the Complaint

Details of Complaint Filed Against (Respondent):

Name of the Person/ Organization:

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/files/documents. Check here if another sheet is attached.

Reporting Status:

Did you report this complaint to the concerned or to any other organization

Name of the person to whom complaint was reported

Contact Details

Email

Address:

Date of reporting the complaint:

Action taken

Complainant's Signature

Date: ……..

Please submit the copy of the report by
Mail: ……
Complete Address of the Appropriate Authority
Email: ……
For any Query
Complaint Hotline No.: ……

FORM 11
Consent for Posthumous Retrieval of Sperm

Application requirements for posthumous use:

1. A completed application form
2. A copy of a counselling report of surviving partner;
3. A copy of the applicant's deceased partner's death certificate;
4. Evidence of the applicant's relationship with their deceased partner (if not stated on the death certificate); eg: marriage certificate
5. Evidence of the applicant's deceased partner's written consent to posthumous use of gametes and/or embryos.

Conditions:

1. The intending/commissioning couple was registered for ART procedures in a clinic for undergoing ART and have provided prior written consent for posthumous retrieval of sperms. The deceased male who would undergo the treatment procedure should have received, during his life time, counselling by a counsellor providing services on behalf of a registered provider, in relation to the prescribed matters; and
2. Consent may be withdrawn at any time before the treatment procedure or action consented to is carried out.

Consent Form for Posthumous use of Gametes

We _____ hereby give our consent for the retrieval of sperms after the death of Mr……..(name of husband/partner) . We have had a full discussion with Dr. _____ (name and address of the clinician) on _____.We have been explained in detail about the procedures involved and we have been counselled by _____ (name and address of independent counsellor) on _____. We understand that posthumous reproduction involves retrieval of sperms from the deceased male for the purpose of having a child by the Surviving partner. We also understand that the child thus born using these sperms will be our legitimate child and will have all the same equal rights to a child born naturally.

Endorsement by the ART Clinic/ ART Bank

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: _____

Huband

Wife

Name, Address and Signature of the Witness from the Clinic

Name and Signature of the Doctor

Date: ……..

Place: ……

FORM -12
Consent Form to be Signed by the Couple/Woman

I/We have requested the clinic……..…… ……..……. (name &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 retreival.
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 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 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 – 13
Consent for Intrauterine Insemination with Husband's Semen/ Sperm

_____ 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 – 14
Consent for Intrauterine Insemination with Donor Semen

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 – 15
Consent for Freezing of Embryos

I/We, _____ and _____, consent to freezing of the embryos that have resulted out of –ART with sperm of _____ & oocyte of _____. We understand that the embryos would be normally kept frozen for ten 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**

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 / ☐

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

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

   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 disposition of my Cryopreserved embryos. as follows:
   Cryopreserved embryos. to be removed from storage for subsequent disposal (yes/no) ____. ____

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 as it is listed in the clinical records at clinic can conclude that I am no longer interested in storing these specimen(s) and I hereby instruct the clinic to dispose of my Cryopreserved embryos.

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 dispose of the Cryopreserved embryos. as follows:

(i) to remove from storage for subsequent disposal (yes/no) ____ _____ _____

(ii) If No to (i) above, proceed to (ii) to (iv) below

(iii) to be used to improve assisted reproduction procedures (yes/no) ____ _____ _____

(iv) to be used to provide instruction in assisted reproduction procedures (yes/no) ___ _____ _____

4. 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 16
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) dispose them off. 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 transferred.

***Husband / Man**

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

To perish	☐
To be 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/ 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

Name and Address of the ART Clinic

*The appropriate option may be ticked

Date: ……

Place: ……

Terms and Conditions

Patient's Agreement

1. Provision of Information
   As long as I have cryopreserved gametes 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, and intention regarding my cryopreserved gametes. 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;
   (iii) provide a new address or forwarding 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 disposition of my Cryopreserved

Gametes as follows:

2. Payment of Fees
I understand that I am responsible for the costs of cryopreservation and storage of my Cryopreserved Gametes. 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 Gametes remain unpaid for a period of one year after the first invoice is forwarded to my address as it is listed in the clinical records at clinic can conclude that I am no longer interested in storing these specimen(s) and I hereby instruct the clinic to dispose of my Cryopreserved Gametes.

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 dispose of the Cryopreserved Gametes as follows:
(i) to remove from storage for subsequent disposal (yes/no) ____ _____ _____
If No to (i) above, proceed to (ii) to (iv) below

4. 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 17 (for minors)
Assent for Freezing of Gametes Sperm/Oocytes & 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, 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) dispose them off. 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:

Parents / Legal Guardian

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

To perish ☐

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

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

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, 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 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 disposition disposal 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 ~~annual~~ 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 as it is listed in the clinical records at clinic can conclude that I am /we are no longer interested in storing these specimen(s) and I hereby instruct the clinic to dispose of my Cryopreserved Gametes.

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 dispose of the Cryopreserved Gametes as follows:

(i) to remove from storage for subsequent disposal (yes/no) ____ _____ _____

If No to (i) above, proceed to (ii) to (iv) below **to be given for research purpose**

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 18
CONSENT FORM FOR WITHDRAWAL

(For Commissioning Couples /women)

Name: Spouse Name (Husband/Wife/none):
DOB: DOB:
Age: Age:

I wish to withdraw the consent given for

1. **ART Procedure**_____ (name of the procedure/treatment)

2. **Use of my/donor oocytes**
   For self-use ☐
   Research purposes
   To perish
3. **Use of my/ donor sperms**
   Self-use ☐
   Research purposes ☐
   To perish

Withdrawing my consent to the use or storage of my oocyte, sperm or embryos.
I am aware that by my consent to storage, I automatically consent to allow my oocyte/sperm or embryos to perish. If I withdraw my consent to the storage of embryos, and the embryos were to be used for my partner's or someone else's treatment, they will be notified of my withdrawal I have already paid the amount due towards medical and other expenses related to stimulation of oocyte donor

Specific Reasons for withdrawing

_____
_____
_____

Signature of the Patient

Signature of Spouse (husband/wife, if any)

Endorsement by the ART Clinic

I/ we have personally explained to _____ and _____ the details and implications of his / her / their withdrawing this consent/ 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

Signature of the Patient

Signature of Spouse (husband/wife, if any)

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

Dated: ……

FORM – 19
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 19 A

For Oocyte Donors AADHAR card no. to be entered

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

Form – 19 B

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 - 20

Results of screening of Semen Donors / Oocyte Donors

(To include every individual screened)

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

*A: Semen donation
B: Oocyte donation

+ Name and signature of the person certifying suitability or otherwise

FORM - 21
Consent for Oocyte Retrieval

Name(s) and address(es) of commissioning woman

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

3. The mixing of the following using ART procedures

☐	My oocytes	☐	the sperm of my husband
☐	Anonymous donor oocyte	☐	anonymous donor sperm

4. 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

(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 woman ~~Person~~

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 - 22
Consent Form for the Donor of Sperm

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.) Wife's consent should be taken

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: …….

FORM –23
Consent Form for the Donor of Oocytes

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:

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.

(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.

Name, address and signature of the Witness from the clinic

Name and signature of the Doctor

Name and address of the ART clinic

Date: ……

FORM 24 A
Information on Semen Donor

Date of filling the form:

Basic Information

1. Identification number (Donor ID)
2. Age / Date of birth
3. Adhar No.
4. Place of birth:
5. Marital status
6. Education
   - i) Donor
   - ii) Spouse
7. Occupation
   - i) Donor
   - ii) Spouse
8. Monthly income
9. Religion
10. Address
11. Telephone
12. Email

History

13. Obstetric history of wife:
    - i) Number of deliveries
    - ii) Number of abortions
    - iii) Other points of note
14. History of use of contraceptives
15. Medical history
16. Family history from the medical point of view
17. History of any abnormality in a child of the donor
18. History of blood transfusion
19. History of substance abuse.
20. History of any Genetic abnormality, if available, any results of tests undertaken in relation to that abnormality.

Investigations

21. Blood group and Rh status
22. Complete blood picture:
    - i) Hb
    - ii) Total RBC count
    - iii) Total WBC count

iv) Differential WBC count
v) Platelet count
vi) Peripheral smear

23. Random blood sugar
24. Blood urea / Serum creatinine
25. SGPT
26. Routine urine examination
27. HBsAg status
28. Hepatitis C status
29. HIV [(1)] status with date of the tests done
30. Hemoglobin A2 (for thallasemia) status
31. HIV PCR [(2)] (positive or negative)
32. Sexually transmitted diseases
33. Any other specific test [(3)]

Features

34. Height
35. Weight
36. Colour of skin
37. Colour of hair
38. Colour of eyes

Detailed Physical Examination

39. Pulse
40. Blood pressure
41. Temperature
42. Respiratory system
43. Cardiovascular system
44. Per abdominal examination
45. 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 – 24 B
Information on Oocyte Donor

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. Aadhar No.
4. Place of birth:
5. Marital status
6. Education:
   i) Donor
   ii) Spouse
7. Occupation
   iii) Donor
   iv) Spouse
8. Monthly income
9. Religion
10. Address
11. Telephone
12. Email

History

13. Obstetric history
    i) Number of deliveries
    ii) Number of abortions
    iii) Other points of note
14. Menstrual history
15. History of use of contraceptives
16. Medical history
17. Family history from the medical point of view
18. History of any abnormality in a child of the donor
19. History of blood transfusion
20. History of substance abuse
21. History of any Genetic abnormality, if available, any results of tests undertaken in relation to that abnormality

Investigations

22. Blood group and Rh status
23. Complete blood picture:
    i) Hb
    ii) Total RBC count
    iii) Total WBC count
    iv) Differential WBC count
    v) Platelet count
    vi) Peripheral smear
24. Random blood sugar
25. Blood urea / Serum creatinine
26. SGPT
27. Routine urine examination
28. HBsAg status
29. Hepatitis C status
30. HIV status with date of the tests done
31. Hemoglobin A2 (for thallasemia) status
32. Any other specific test [(2)]
33. Sexually transmitted diseases

Features

34. Height
35. Weight
36. Colour of skin
37. Colour of hair
38. Colour of eyes

Detailed Physical Examination

39. Pulse
40. Blood pressure
41. Temperature
42. Respiratory system
43. Cardiovascular system
44. 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