[To be published in the Gazette of India, Extraordinary, Part II, Section-3, Subsection (ii)]

# 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 50 of the Surrogacy (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 Surrogacy (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 Surrogacy (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;

## 3. The prescribed expenses under clauses (b), (f) and (q) of sub-section (1) of section 2;

- 3.1 Medical expenses- cost related to medical procedures related to surrogacy.
- 3.2 Expenses arising due to any possible complication that may arise in pregnancy, delivery and postpartum.
- 3.3 Expenses covering any possibility of maternal mortality.
- 3.4 Legal expenses required for parental order and birth affidavit.
- 3.5 Miscellaneous expenses-, travel, follow-up charges, loss to wages.

## 4. The minimum qualifications for persons employed at a registered surrogacy clinic under clause (*iii*) of section 3;

Minimum requirement of staff and their qualification for Surrogacy clinics shall conform to the requirement as specified in Schedule I, Part-1

5. The period and manner in which a person shall store human embryo or gamete under clause (*vii*) of section 3;

The manner of storage of embryos and gametes will be such as specified in Schedule I, Part 2.

6. The form and manner of application for obtaining certificate of recommendation from the Board under proviso to sub-clause (a) of clause (ii) of section 4;

The manner of application for obtaining a certificate of recommendation as specified in Form 1.

7. The insurance coverage in favour of the surrogate mother from an insurance company and the manner of such coverage under item (*III*) of sub-clause (a) of clause (iii) of section 4;

8. The number of attempts of surrogacy procedures under the proviso to item (*III*) of sub-clause (*b*) of clause (*iii*) of section 4;

The number of attempts of any surrogacy procedure on the surrogate mother will not be more than three times.

9. The form in which consent of a surrogate mother has to be obtained under clause (ii) of section 6;

The consent of a surrogate mother has been specified in Form 2.

10. The number of embryos to be implanted in the uterus of the surrogate mother under section 9;

The gynecologist shall transfer one embryo in the uterus of a woman during a treatment cycle. However only in explainable circumstances up to three embryos may be transferred.

11. The conditions under which the surrogate mother may be allowed for abortion during the process of surrogacy under section 10;

The conditions will be as per the MTP (Amendment) Act, 2021.

12. The form and manner in which an application shall be made for registration and the fee payable thereof under sub-section (2) of section 11;

12.1 An application for registration shall be made by the Surrogacy Clinics to the Appropriate Authority in Form 3.

Every application for registration shall be accompanied by an application fee of Rupees 5, 00,000 for Surrogacy Clinic

PROVIDED that if an application for registration of any surrogacy clinic etc., 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. The application fee once paid will not be refunded.

- 13. The facilities to be provided, equipment, and other standards to be maintained by the surrogacy clinics under sub-section (4) of section 11;
- 13.1 The facilities and equipment at a Surrogacy clinic are specified under Schedule 1 Part 3.
- 13.2 Minimum Physical Infrastructure Requirement for Surrogacy clinic

Minimum physical infrastructure for the Surrogacy clinic shall conform to the requirement as specified in Schedule I, Part-4.

- 14. The period, manner and form in which a certificate of registration shall be issued under sub-section (1) of section 12;
- 14.1 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 4 to the applicant. One copy of the certificate of registration shall be displayed by the registered Surrogacy at a conspicuous place at its place of business.
- 14.2 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 Form 5.
- 14.3 In such a case of 14.2 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.

- 14.4 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 Surrogacy clinic, both copies of the certificate of registration shall be surrendered to the Appropriate Authority.
- 14.5 In the event of change of ownership or change of management of the Surrogacy clinic the new owner or manager of such clinic shall apply afresh for grant of certificate of registration.
- 15. The manner in which the certificate of registration shall be renewed and the fee payable for such renewal under sub-section (3) of section 12:
- 15.1 An application for renewal of certificate of registration shall be made in duplicate in Form 3, to the Appropriate Authority 60 days before the date of expiry of the certificate of registration.
- 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, 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 5,00,000 for Surrogacy Clinic

PROVIDED that if an application for registration of any Surrogacy clinic., 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.

- 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 itself, it shall, for reasons to be recorded in writing, reject the application for renewal of certificate of registration and communicate such rejection to the applicant as specified in Form 5 within 30 days from the date of application of renewal.
- 15.5 In such a 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 Surrogacy clinic.
- 15.7 In case of failure of renew of the registration, the Surrogacy clinic would be given time to complete the ongoing surrogacy procedure 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 Surrogacy clinic would transfer all the stored gametes/embryos to another registered Surrogacy clinic
- **16.** The manner in which an appeal may be preferred under section 14; The format of appeal will be as specified in Form 6

## 17. The procedures for conducting an inquiry against the Members under sub-section (2) of section 21;

17.1. The proceedings against a non ex officio member of the National Board on receipt of a complaint will be conducted as per the directions of the Chairperson of the National Board.

### 18. The conditions under which a Member of the Board eligible for reappointment under section 24;

- 18.1 A committee will be constituted as directed by the Chairperson/ Central Government for holding a preliminary enquiry against the member of the board.
- 19.1 The reappointment of any of the ten expert members nominated to the National Board will be considered as per the decision of the Central Government in consultation with the Chairperson of the National Board.
- 19.2 The criteria for reappointment will depend on the performance and support provided by the said member in the preceding tenure.

#### **General Conditions of reappointment:**

- 1. Age should not be more than 65 years.
- 2. Age relaxation will be in accordance with Central Government of India instructions.
- 3. No criminal proceeding is either pending or contemplated against the member in any Court of Law.

#### 20. The other functions of the Board under clause (g) of section 25;

20.1 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 surrogacy and to assist the State Boards in accreditation, supervision and regulation of services of surrogacy clinics in the country.

- 20.2 To encourage and promote of training and research in surrogacy.
- 20.3 To assist the central government in issuing guidelines, notifications, and orders pertaining to Surrogacy.
- 20.4 Any other activities as directed by the central government.
- 21. The manner in which reports shall be furnished by the State Assisted Reproductive Technology and Surrogacy Board and the Union territory Assisted Reproductive Technology and Surrogacy Board to the Board and the Central Government under clause (iii) of section 26; The manner in which reports shall be furnished by the State Assisted Reproductive Technology and Surrogacy Board and the Union territory Assisted Reproductive Technology and Surrogacy Board to the Board and the Central Government is specified under Form 7
- 22. The other functions of the State Board under clause (iv) of section 26;
- 22.1 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 Surrogacy.
- 22.2 The State/UT board shall supervise in accreditation and regulation of services of Surrogacy clinic in their respective state/UT.
- 22.3 Any other activities as directed by central government.
- 23. The procedures for conducting an inquiry against the members of State/UT Board under sub-section (2) of section 31;

The proceedings against a non ex officio member of the State/UT Board on receipt of a complaint will be conducted as per the directions of the Chairperson of the State/UT Board.

A committee will be constituted as directed by the Chairperson/ State/UT Government for holding a preliminary enquiry against the member of the board.

- 24. The conditions under which the members of State Board is eligible for re-appointment under section 34;
- 24.1 The reappointment of any of the ten expert members nominated to the State/UT Board will be considered as per the decision of the State Government in consultation with the Chairperson of the State/UT Board.
- 24.2 The criteria for reappointment will depend on the performance and support provided by the said member in the preceding tenure.

#### **General Conditions of reappointment:**

- 1. Age should not more than 65 years.
- 2. Age relaxation will be in accordance with State Government of India instructions.
- 3. No criminal proceeding is either pending or contemplated against the member in any Court of Law.

### 25. Empowering the appropriate authority in any other matter under clause (d) of section 36;

- 25.1 In case required, advisory committee may be constituted for addressing local issues related to Surrogacy clinics.
- 25.2 Any other activities as directed by the Central Government, National Board, State Board.

## 26. The other powers of appropriate authority under clause (d) of subsection (1) of section 37;

- 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 37 of the Surrogacy (Regulation) Act, 2021.
- 26.2 Any other powers as delegated by the Central Government, National Board, State Board.
- 26.3. Code of conduct to be observed by Appropriate Authority
  - All Appropriate Authorities notified under the Act, inter-alia, shall observe the following code of conduct with respect to the Advisory Committees, namely: -
  - 26.3.1 ensure that a person who is the part of investigating machinery in cases under Surrogacy (Regulation) Rules, 2022, shall not be nominated or appointed as a member of the Advisory Committee;
  - 26.3.2 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;
- All Appropriate Authorities notified under the Act, inter-alia, shall observe the following conduct for processing complaint and investigation, namely:
  - 26.4.1 maintain appropriate diaries in support of registration of each of the complaint or case under the Act;
  - 26.4.2 attend to all complaints and maintain transparency in the followup action of the complaints;
  - 26.4.3 Initiate investigation on each of the complaint within twenty-four hours of receipt of the complaint and complete the investigation

within 7 working days of receipt of such compliant;

- 26.5 All the Appropriate Authorities notified under the Act, inter-alia, shall follow the following financial guidance, namely:
  - 26.5.1 maintain a separate and independent bank account operated by two officers jointly.
- 27. The particulars of the details of registration of surrogacy clinics, cancellation of registration, etc., in such format under sub-section (2) of section 37;

The registration of the Surrogacy clinic will be as prescribed in Form 3. The cancellation of registration as issued by appropriate authority as prescribed in Form 8.

28. The manner of giving notice by a person under clause (b) of subsection (1) of section 44;

The person including a social organization or an individual may give notice to the appropriate authority as per the Form 9

29. Period up to which record charts etc. shall be preserved under sub section (1) of section 46

The surrogacy clinics shall preserve the record, charts, forms, reports, consent forms, agreements and other documents for a period of 25 years and if required beyond this period after seeking due permission from the National Board.

30. Manner in which the seizure of documents, records, objects, etc., shall be made and the manner in which seizure list shall be prepared and delivered under subsection (1) of section 47

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

- 31. Any other matter which is to be, or may be, or in respect of which provision is to be made by rules
- 31.1 Public Information
  - 31.3.1. At least one copy each of the Act and these rules shall be available on the premises of every surrogacy and shall be made available to

the clientele on demand for perusal.

31.3.2. The Appropriate Authority, the Central Government, the State Government, and the Government/Administration of the Union Territory may publish periodically lists of registered Surrogacy clinics 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 ensuring anonymity /confidentiality of patients.

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

- 31.3 Application for Indian Origin or an intending woman to avail surrogacy
  The Application for Indian Origin or an intending woman to avail surrogacy
  as specified in Form No 10 & 10A
- 31.4 Medical Indications necessitating Gestational Surrogacy Surrogacy can be opted if:
  - 31.4.1 Woman with absent uterus or missing uterus/or abnormal uterus (like hypoplastic uterus/intrauterine adhesions/thin endometrium/ small uni-cornuate uterus, T-shaped uterus) or if the uterus is surgically removed due to any medical conditions such as gynecological cancers.
  - 31.4.2 Intended parents/woman who has repeatedly failed to conceive after multiple IVF/ICSI attempts. (Recurrent implantation failure).
  - 31.4.3 Multiple pregnancy losses resulting from an unexplained medical reason. Unexplained graft rejection due to exaggerated immune response.
  - 31.4.4 Any illness that makes it impossible for woman to carry a pregnancy to viability or pregnancy that is life threatening.
- 31.5 Intimation of changes in employees, place or equipment Every Surrogacy Clinic shall intimate every change of designated employee, place, address and equipment installed, to the Appropriate Authority (at least thirty days in advance of the expected date of such change.
- 31.6 Annual Report
  - The National /State Board shall prepare as per the prescribed format year 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.
- 31.7 Certificate of Essentiality issued by Appropriate Authority

  The certificate of essentiality will be issued by Appropriate Authority as

- prescribed in FORM 11
- 31.8 Certificate of medical indication necessitating surrogacy
  A certificate of a medical indication necessitating surrogacy will be issued
  by District Medical Board as prescribed in Form 12
- 31.9 Parental Order

  An order concerning the parentage and custody of the child shall be as specified in Form 13 & 13 A
- 31.10 Certificate of medical and psychological fitness
  A certificate of medical and psychological fitness of the surrogate to
  undergo surrogacy and surrogacy procedures will be as prescribed in Form
  14.
- 31.11 Withdrawal of consent

  The surrogate mother shall have an option to withdraw her consent for surrogacy before the implantation of the embryo in her womb as specified in form 15.
- 31.12 Complaints The format for making a complaint to the appropriate authority against a surrogacy clinic is specified in Form 16.
- 31.13 Eligibility Certificate- The format for eligibility certificate for intending couple/ Intending woman /Surrogate mother to be issued by appropriate authority is as specified in FORM 17 & 17 A.
- 31.14 Written consent for Surrogate for Abortion/Medical Termination of Pregnancy as specified in Form 18.
- 31.15 Screening of the surrogate mother as specified in Form 19.
- 32. Any other functions/matter as directed by the Central Government

#### **SCHEDULE-1 - PART 1**

The staff requirements given below will be mandatory for all Surrogacy Clinics.

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

#### 32.1 Gynecologist

- 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 super specialist DM /fellowship in reproductive medicine or experience of not less than 03 years in reproductive medicine.
- 32.1.2 Understanding of the causative factors of male and female infertility.
- 32.1.3 Knowledge of the practice and use of diagnostic methods for determining the cause of infertility.
- 32.1.4 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.
- 32.1.5 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.
- 32.1.6 Must be knowledgeable about the principles of ovarian stimulation and the management of complications arising thereupon.
- 32.1.7 The following responsibilities of the gynecologist will include.
  - Interviewing of the infertile couple initially.
  - History taking.
  - Physical examination of the female.

- Recommending appropriate tests to be carried out, interpreting them and treating medical disorders (such as infections and endocrine anomalies).
- Carrying out gynecological endoscopy and ultrasonographic intervention for diagnosis and therapy of infertility.
- Carrying out ART procedure and other ancillary procedures as the case and facilities may warrant, based on diagnostic evidence.
- The ART specialist should do self-appraisal by maintaining records for audit.

#### 32.2 Andrologist

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). The additional experience includes.

- 32.2.1 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.
- 32.2.2 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.
- 32.2.3 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.
- 32.2.4 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:

- 1. Recording case histories.
- 2. Prescribing appropriate diagnosis and treatment based on the diagnosis.
- 3. Carrying out such surgical procedures as warranted by the diagnosis.
- 4. Maintaining all the records, from the case history to the treatment given, and the patient consent forms.
- Referring the couple to the gynecologist for carrying out the appropriate ART procedure, if necessary, after the male factor has been duly investigated.
- 6. Referring the couple to the counsellor if necessary.

#### 32.3 Senior Embryologist

32.3.1 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.

- 32.3.2 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.
- 32.3.3 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.
- 32.3.4 To maintain records of all the procedures carried out in the laboratory.

#### 32.4 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.

#### 32.5 Counselor

32.5.1 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 Surrogacy. A member of the staff of a Surrogacy Clinic who is not engaged in any other full-time activity in the clinic can act as a counsellor.

#### 32.5.2 The additional experience includes:

32.5.2.1 The counsellor must invariably apprise the couple of the advantages of adoption as against resorting to Surrogacy. An individual may act as a counsellor for more than one Surrogacy Clinic but each clinic where the counsellor works must own responsibility for the counsellor and ensure that the counsellor is able to take care of the entire counselling load of the clinic without compromising on the quality of the counselling service. 32.5.2.2 In Surrogacy clinics 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 that may be born following such treatment. and any children

#### 32.6 Anesthetist

a MD/ DA Anesthetist should have 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.

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

- a) Known drug allergies
- b) Previous problems with anesthetics or sedatives
- c) Airway assessment
- d) Whether the patient is taking any regular medication

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

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

#### 32.7 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 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 program me coordinator / director should have a post-graduate degree in an appropriate medical or biological science. In addition, he / she must have a reasonable experience of Surrogacy/ART. Deficiency of the services of Director would be considered punishable.

#### **SCHEDULE-1 - PART 2**

#### 33. The manner of storage of embryos and gametes will be as follows:

- Prior to the processing of patient gametes or embryos, intended for use in treatment or storage, the center must:
- 33.2 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.
- 33.3 Semen culture shall be carried out on all semen samples before preservation
- 33.4 Devise a system of storage of gametes and embryos clearly separating
  - 33.4.1 quarantined
  - 33.4.2 unscreened

- 33.4.3 tested positive
- 33.4.4 tested negative
- 33.5 The center should have a separate storage facility of the gametes in case of HIV, Hepatitis, HCV and other such infected patients.
- 33.6 The center should ensure that the storage facilities for gametes and embryos:
  - 33.6.1 are dedicated for the purpose, and adequate for the volume and types of activities
  - 33.6.2 are designed to avoid proximity to ionizing radiation (radioactive material), any known potential source of infection and chemical /atmospheric contamination
  - 33.6.3 have a storage-location system that minimizes the amount of handling required to retrieve gametes and embryos.
- 33.7 The center should also have procedures to deal with emergency situation that may cause damage to storage vessels, failure of storage conditions or both.
- 33.8 The center's documented procedures should also ensure that:
  - 33.8.1 gametes and embryos are stored under controlled conditions that are validated and monitored.
  - 33.8.2 gametes and embryos are packaged for storage in a way that prevents any adverse effects on the material and minimizes the risk of contamination.
  - 33.8.3 records are kept indicating every occasion when gametes and embryos are handled during storage and release, and by whom.
  - 33.8.4 records are kept indicating that gametes and embryos meet requirements for safety and quality before release.
- 33.9 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.
- 33.10 The center should have adequate staff and funding for an 'on-call' system for responding to alarms out of hours, and adequate spare storage capacity to enable transfer of samples when required.
- 33.11 All the centers having facility should have emergency back up plan to handle these gametes / embryos in case of power failure/ fire breakout.
- 33.12 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.
- 33.13 Transfer of stored gametes and embryos from one Surrogacy clinic to another Surrogacy clinic can be permitted after permission from the National Board along with transfer of all records with appropriate consent and acceptance of both registered Surrogacy clinics.
- 33.14 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.

#### **SCHEDULE-1 - PART 3**

#### 34. Requirement of Equipment

- 34.1 Facility for control of temperature & humidity (Air handling unit)
- 34.2 Filtered air with an appropriate number of air exchanges per hour
- 34.3 Wall and floors are composed of materials that can be easily washed and Disinfected
- 34.4 A laminar flow bench with a thermostatically controlled heating plate
- 34.5 An IVF grade Stereo Microscope preferably with CCD camera and recording software
- 34.6 A routine high powered Trinocular light microscope (IVF grade and preferably with CCD camera and recording software)
- 34.7 A high-resolution inverted microscope with phase contrast or Hoffman Optics (with standard IVF grade objective), preferably with facilities for video recording
- 34.8 A micromanipulator (if ICSI is done)
- 34.9 A CO2 incubator, preferably with a backup
- 34.10 A laboratory centrifuge
- 34.11 Equipment for freezing embryos
- 34.12 Liquid nitrogen cans for IVF
- 34.13 Liquid nitrogen cans for Infected samples
- 34.14 A pharmaceutical refrigerator
- 34.15 Heating plates
- 34.16 Test tube heater
- 34.17 Heating blocks
- 34.18 Alloy blocks/ Plates
- 34.19 Biometrics (to restrict the entry)

#### **SCHEDULE-1 - PART 4**

#### 35. Minimal Physical Requirements for a Surrogacy Clinic

#### Flowchart below explains physical requirement of each clinic

	General	Laboratory	Requirement	Sterile Area
	Requirements	services	for clean area	
Surrogacy	1. Reception Area,	1. General	1. IUI room	1. Semen
Clinic	Waiting Room	purpose	2. Semen	processing
	2. Consulting	clinical	collection	laboratory
	Room,	laboratory	room	2. Operation
	3. Examination	(inhouse/		Theatre
	Room with	referral)		3. IVF/culture
	privacy	2. Blood		Laboratory
	4. Storage Room	collection		4. Embryo
	5. Records Room	Area		transfer
	6. Fire Safety			Laboratory
	arrangement			5. Autoclaving
				room

A well-designed Surrogacy clinic 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.

- 35.1 Reception & Waiting Area -
- 35.2 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 gynecological instruments for examining the female per vaginum, and an appropriate ultrasonographic machine.
- 35.3 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 attached toilet and must not be used for any other purpose.
- 35.4 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.
- 35.5 Clean room for IUI room: It should have a gynaecology examination table and appropriate lights arrangement There must be a separate area/room with an appropriate table for Intra-Uterine Insemination (IUI).
- 35.6 General purpose clinical laboratory (in house/referral) with a Blood Collection Area- The Surrogacy clinic must have ready access to laboratories that are able to carry out immunoassays of hormones (FSH, LH, Prolactin, hCG, TSH, Insulin, Estradiol, Progesterone, Testosterone and DHEA) and tests such as for HIV and Hepatitis B. Endocrine evaluation constitutes an essential diagnostic procedure to determine the cause of infertility. It is also necessary to estimate blood estradiol in samples taken from a woman undergoing controlled ovarian hyperstimulation, and have the result on the same day to determine the dose of drugs to be given for induction of ovulation. Accurate monitoring of endocrine response to controlled ovarian stimulation goes a long way in preventing ovarian hyperstimulation.
- 35.7 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.
- 35.8 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.
- 35.9 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.
- 35.10 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.

- 35.11 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:
  - 35.11.1 A laminar flow bench with a thermostatically controlled heating plate
  - 35.11.2 A stereo microscope
  - 35.11.3 A routine high-powered binocular light microscope
  - 35.11.4 A high-resolution inverted microscope with phase contrast or Hoffman optics, preferably with facilities for video recording
  - 35.11.5 A micromanipulator (if ICSI is done)
  - 35.11.6 A CO2 incubator, preferably with a back up
  - 35.11.7 A hot air oven
  - 35.11.8 A laboratory centrifuge
  - 35.11.9 Equipment for freezing embryos
  - 35.11.10 Liquid nitrogen storage tanks
  - 35.11.11 A refrigerator

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.

All material from the operation room, culture dishes and Falcon tubes for sperm collection (including lids), must bear the name of the patient. In the incubator, identified oocytes and sperm should be kept together on the same tray and double-checked.

Pipettes used should be disposed off immediately after use. The embryology laboratory must have daily logbook in which all the day's activities are recorded, including the performance of the equipment.

- 35.12 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.
- 35.13 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.

- 35.14 Fireproof cabinets can be used maintaining records and fire safety arrangements.
- 35.15 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.
- 35.16 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.
- 35.17 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.
- 35.18 Back-up facility There should be no interruption in power supply to the incubator and to other essential services.

## FORM 1 CERTIFICATE OF RECOMMENDATION TO THE INTENDED COUPLE OF INDIAN ORIGIN AND INTENDING WOMAN (DIVORCEE/WIDOW)

Certificate granted to Mrs	yrs.				. Aged of
I, Dr of . Board) hereby certify that the Mrs suffering from		& Mr		have	e been
(Medical Condition) since last couple have not been able to conc requiring to undergo surrogacy proce	eive a chi	ld by any	other me	ans and	
Medical History:					
I hereby recommend that the coup availing surrogacy services for their t			to a suri	rogacy cli	nic for
Declaration					
I hereby state that information given medical condition and that the facts knowledge.				-	
Signature & Seal:					
Name of Medical Officer Registration No. Address: Telephone No: Date of referral:					
Place:					

## Form 2 Consent of the Surrogate Mother & Agreement for Surrogacy

l,					(the wom	ıan), age	ed	years
with	the	consent	of	my	husba	and*	(name),	of
(addres	ss)			. (Aadhar	Number)	), having	ı (Nu	ımber of
childrer	n) child/ d	children (a	ige in y	ears) of	my own	have a	greed to a	act as a
surroga	ite moth	er for Inten	ding c	ouple/inte	ending v	vomen	Name H	Husband
Name -		Wife/	Intendin	g women	Age H	usband	Age	)
	Wife/Inte	ending women			had	a full d	iscussion	with Dr.
					of the	Surro	gacy cli	nic on
		ir	regard	to the m	natter of	my actir	ng as a s	urrogate
mother	for the ch	nild/children of	the abov	ve couple.				

- 1. That I understand that the methods of treatment may include:
  - a) Stimulation of the genetic mother for follicular recruitment
  - b) The recovery of one or more oocytes from the genetic mother by ultrasound-guided oocyte recovery or by laparoscopy.
  - c) The fertilization of the oocytes from the genetic mother with the sperm of her husband.
  - d) The fertilization of a donor oocyte by the sperm of the husband.
  - e) The maintenance and storage by cryopreservation of the embryo resulting from such fertilization until, in the view of the medical and scientific staff, it is ready for transfer.
  - f) Implantation of the embryo obtained through any of the above possibilities into my uterus, after the necessary treatment if any.
- That I have been assured that the genetic mother and the genetic father have been screened for HIV and hepatitis B and C and other sexually transmitted diseases before oocyte recovery and found to be seronegative for all these diseases. I have, however, been also informed that there is a small risk of the mother or / and the father becoming seropositive for HIV during the window period.
- 3. That I consent to the above procedures and the administration of such drugs that may be necessary to assist in preparing my uterus for embryos transfer, and for support in the luteal phase.
- 4. That I understand and accept that there is no certainty that a pregnancy will result from these procedures.

- 5. That I understand and accept that the medical and scientific staff can give no assurance that any pregnancy will result in the delivery of a normal and living child/children.
- 6. That I am unrelated/ related (relation) \_\_\_\_\_ to the couple (the would-be genetic parents).
- 7. That I have worked out medical expenses and conditions of the surrogacy with the couple in writing and an appropriately authenticated copy of the agreement has been filed with the clinic, which the clinic will keep confidential. An insurance coverage of such amount and in such manner as will be prescribed in favour of the surrogate mother for a period of thirtysix months covering postpartum delivery complications from an insurance company or an agent recognised by the Insurance Regulatory and Development Authority established under the Insurance Regulatory and Development Authority Act, 1999;
- 8. That I agree to relinquish all my rights over the child and hand over the child/children to \_\_\_\_\_\_\_, or \_\_\_\_\_\_ and \_\_\_\_\_\_\_ in case of a intending couple, or to \_\_\_\_\_\_\_ in case of their separation during my pregnancy, or to the survivor in case of the death of one of them during pregnancy, or to ------- in case of death of both of them, or to ------ in case of guarantor intending couple/ women , as soon as I am permitted to do so by the hospital / clinic / nursing home where the child/ children are delivered.
- 9. That I have been provided with the written consent of all of those name(s) mentioned above.
- 10. That I undertake to inform the Surrogacy Clinic, \_\_\_\_\_\_, of the result of the pregnancy.
- 11. That I take no responsibility that the child /children delivered by me will be normal in all respects. I understand that the biological parent(s) of the child/ children has / have a legal obligation to accept the child/ children that I deliver and that the child/ children would have all the inheritance rights of a child/ children of the biological parent(s) as per the prevailing law.
- 12. That I will not be asked to go through sex determination tests for the child/ children during the pregnancy and that I have the full right to refuse such tests.
- 13. That I understand that I would have the right to terminate the pregnancy in case of any complication as advised by the doctors, under the provisions of the MTP Act;
- 14. That I certify that (a) I have not beared any child through surrogacy before.
- 15. That I have been tested for HIV, hepatitis B and C and shown to be seronegative for these viruses just before embryo transfer.
- 16. That I will not have intercourse of any kind once the cycle preparation is initiated.

- 17. That I certify that (a) I have not had any drug intravenously administered into me through a shared syringe; and (b) I have not undergone blood transfusion in the last six months.
- 18. That I also declare that I will not use drugs intravenously, or undergo blood transfusion excepting of blood obtained through a certified blood bank on medical advice.

	medical advice.
19.	That I undertake not to disclose the identity of the party seeking the surrogacy.
20.	That In the case of the death or unavailability of any of the party seeking my
	help as the surrogate mother, I will deliver the child/children to
	or
	in this order; I will be provided, before the embryo transfer into me, a written agreement of the above persons that they will be legally bound to accept the child/ children in the case of the above-mentioned eventuality. (If applicable) My husband (Name - ) (Aadhar car number-) has approved my acting as a surrogate.
(Strike	e off if not applicable.)
•	rsement by the Surrogacy Clinic
Lilao	isoment by the ourrogacy clime
I/we h	ave personally explained to and and
	etails and implications of his / her / their signing this consent / approval form,
	nade sure to the extent humanly possible that he / she / they understand these
details	s and implications.
Signe (Surre	ed: ogate Mother)
	e, address and signature Witness from the Surrogacy clinic
Name	and signature of the Doctor
Name	and address of the Surrogacy Clinic

Dated:

#### FORM 3

## Application Form for

#### Registration or Renewal of Registration of a Surrogacy Clinic

#### **SECTION- I (GENERAL INFORMATION)**

ution:
only):
linic):
dertaking prities
5) of Reg. IM-YY)

		Bio-Medical Waste			
	3	(Management and			
		Handling) Rules			
	4	Clinical Establishment Act			
	5	NOC from Fire Safety			
		Department			
4.	1. Ye	2.110			
5.	If yes	, then please provide the Nar	ne and Ad	ddress of the hospi	tal/Institution
6.	within	her your hospital/Institution is the country	having m	ore than one Surro	ogacy clinics
	1. Ye	s 2. No			
7.	-	, then please indicate whethe ad Clinic 2. Sub	r your Su -clinic/Bra		
8.		d clinic, please specify total n Clinic	umber of	sub-clinics/branch	es under
9.	branc	e give the name, address hes which are situated in d clinic.			

#### **SECTION - II (MANPOWER)**

#### **Details of the Staff Available at your Surrogacy 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

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

	-		
1			
Note:	Please enter the code in the	given box and write degre	ee in the space
given al	pove.)		
Whethe	r your Surrogacy Clinic has (	Gynecologist	
1. Yes	2. No		
lf yes, p	lease indicate the total numb	er of Gynecologists	
Give the	e details of qualification of Gy	necologists	
Qualific	<u>cation</u>		
Please	indicate the highest qualificat	tion/degree	
(1)	(2)	(3)	(4)
SI.	Name of the degree	Area/Discipline	Experience in
No.	1. DM/M.Ch.	1. Obst. & Gynecology	ART
	2. MD/MS/DNB	2. Any other	(in yrs)
	3. PG Diploma		
	4. Any other		
1			
2			
3			
<b>(</b> Whethe	(i) Please enter the code in a space given above.  (ii) If more than three, then play your Surrogacy Clinic has A	ease add separate sheets	
1. Yes	2. No		
•			
Jive ine	•	number of Andrologists	
Ouglifia	e details of qualification of An	_	
Qualific	e details of qualification of An	drologist	w from Serial
If more	e details of qualification of An cation than one Andrologist then e	enter the information belo	w from Serial
If more	e details of qualification of An	enter the information belo	w from Serial
lf more no. 2 or	e details of qualification of Ancetion  than one Andrologist then enwards otherwise leave blank	enter the information belo	w from Serial
If more no. 2 or Please	e details of qualification of Ancation than one Andrologist then enwards otherwise leave blank	enter the information belok.	
lf more no. 2 or	e details of qualification of Ancation than one Andrologist then enwards otherwise leave blank indicate the highest qualificat  (2)	enter the information belok. tion/degree (3)	(4)
If more no. 2 or Please (1)	e details of qualification of Ancation than one Andrologist then enwards otherwise leave blank	enter the information belok.  tion/degree  (3)  Area/Discipline	(4) Experience
If more no. 2 or Please (1) SI.	e details of qualification of Ancation than one Andrologist then enwards otherwise leave blank indicate the highest qualificat  (2) Name of the degree	enter the information belok. tion/degree (3)	(4)
If more no. 2 or Please (1) SI.	e details of qualification of Ancation than one Andrologist then enwards otherwise leave blank indicate the highest qualificat  (2)  Name of the degree  1. DM/M.Ch.	enter the information belok.  tion/degree  (3)  Area/Discipline  1. Urology	(4) Experience

1

2

3			
Note:	(i) Please enter the code in space given above.	the given box and write	degree in the
	(ii) If more than three, then pla	assa add sanarata sheets	accordingly
	er your Surrogacy Clinic has (	•	accordingly.
1. Yes	2. No	Similar Embryologist	
	then please indicate the total	number of Clinical Embry	ologist -
•	ne details of qualification of Cli		
	ication	iniodi Embryologiat	
	indicate the highest qualificate	tion/degree	
(1)	(2)	(3)	(4)
SI.	Name of the degree	Area/Discipline	Experience
No.	1.Ph.D./DM/M.Ch.	1. Medicine	(in yrs)
	2.PG/MD/MS/DNB/M.V.Sc.	2. Life Sciences	( ))
	3.PG Diploma	3. Veterinary Sciences	
	4. Diploma	4. Any other	
	5. MBBS/B.V.Sc./B.Sc.		
	6. Any other		
1			
2			
3			
O			
Note:	(i) Please enter the code in th	e given box and write deg	ree in the
	space given above.		
(	ii) If more than three, then ple	ase add separate sheets	accordingly.
Wheth	er your Surrogacy Clinic has (	Counselor	
	es 2. No		
•	then please indicate the total		
	ne details of qualification of Co	ounselor	
	<u>ication</u>		
	indicate the highest qualification		
(1)	(2)	(3)	(4)
SI.	Name of the degree	Area/Discipline	Experienc
No.	1. Ph.D./DM/M.Ch.	1. Social Sciences	(in yrs)
	2. PG/MD/MS/DNB	2. Psychology	
	3. PG Diploma	3. Life Sciences	
	4. Diploma	4. Medicine	
	5. Graduate/MBBS	5. Any other	
	6. Any other		

2			
3			
(Note	: Please enter the code in the given above.)	ven box and write degree	in the space
Whetl	given above.) ner your Surrogacy clinic has Ane	sthetist	
	Yes 2. No	otrotiot	
If yes	then please indicate the total nur	mber of Anesthetist	
•	he details of qualification of Anes		
<u>Quali</u>	<u>fication</u>		
Pleas	e indicate the highest qualification	n/degree	
(1)	(2)	(3)	(4)
SI.	Name of the degree	Area/Discipline	Experience
No.	1. DM/M.Ch.	1. Anesthesiology	(in yrs)
	2. PG/MD/MS/DNB	2. Any other	
	3 P.G Diploma		
	4. Diploma		
	5 Graduate/MBBS		
	6. Any other		
1			
1			
2			

below:

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

#### **SECTION - III (INFRASTRUCTURE)**

- 29. Does your clinic have the following?
  - 1. Yes 2. No
  - a. Reception area
  - b. Waiting room for patients
  - c. Examination room with privacy
  - d. A general-purpose clinical laboratory
  - e. Store room
  - f. Record room
  - g. Autoclave room
  - h. Semen collection room
  - i. Area for changing into sterile garments
  - j. Semen processing laboratory (as per GLP)
  - k. Operation Theatre well equipped for carrying out surgical endoscopy, transvaginal ovum pick-up, Embryo transfer and should be equipped for Emergency resuscitative procedures
  - I. Embryology Laboratory Complex
  - m. Operating table for carrying out the procedures
  - n. Whether the sterile area is air conditioned with fresh air filtered through an appropriate filter system along with ambient temperature of 22°C 25°C (Air Handling Unit)
  - o. Pre and Post operation areas

- p. Bio medical waste disposal system
- *q.* Toilet room for the patients
- r. Lift facility
- s. Fire exit area
- 30. Whether Embryology Laboratory Complex is provided with
  - 1. Yes
- 2. No
- a. Facility for control of temperature & humidity (Air handling unit)
- b. Filtered air with an appropriate number of air exchanges per hour
- Wall and floors are composed of materials that can be easily washed and disinfected
- d. A laminar flow bench with a thermostatically controlled heating plate
- e. An IVF grade Stereo Microscope preferably with CCD camera and recording software
- f. A routine high powered Trinocular light microscope (IVF grade and preferably with CCD camera and recording software)
- g. A high-resolution inverted microscope with phase contrast or Hoffman Optics (with standard IVF grade objective), preferably with facilities for video recording
- h. A micromanipulator (if ICSI is done)
- i. A CO<sub>2</sub> incubator, preferably with a back up
- j. A hot air oven
- k. A laboratory centrifuges
- I. Equipment for freezing embryos
- m. Liquid nitrogen cans for
  - I. IVF
  - II. Infected samples
- n. A pharmaceutical refrigerator
- Heating plates
- p. Test tube heater
- q. Heating blocks
- r. Alloy blocks/ Plates
- s. Biometrics (to restrict the entry)
- t. Temperature
- u. CO<sub>2</sub> analyzer
- v. Volatile Organic Compounds (VOCs) Filtration system
- w. IVF Software
- x. Ovum Pick-Up (OPU) Pump
- y. CCD Monitoring System
- z. IVF Witness System
- aa. Auto-analyzer for Sperm Function Test
- bb. Computer Assisted Semen Analysis (CASA)
- cc. CO<sub>2</sub> and Triple gas Manifold
- dd. Makler Chamber

ee. Cryofreezer ff. Any other (Brief description) gg. Whether you have separate incubators for I. Oocytes II. **Sperms** hh. 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 Whether your Surrogacy Clinic has got hormone assay facility 1. Inhouse 2. Outsource Do you have Microbiology Lab? 1. Inhouse 2. Outsourced Do you have Clinical Chemistry Laboratory? 2.outsourced 1. Inhouse Do you have facility for carrying out Histopathological Studies? 1. Inhouse 2. outsourced Whether an appropriate provision for back-up power supply available at our Surrogacy Clinic 1. Yes 2. No **SECTION - IV (PROCEDURES)** Indicate which of the following Surrogacy procedures are being routinely carried out at your Surrogacy Clinic 1. Yes No *In vitro* Fertilization-Embryo Transfer (IVF-ET) a. b. Altruistic Surrogacy C. Intra-cytoplasmic Sperm Injection (ICSI) Percutaneous Epididymal Sperm Aspiration (PESA) d. Microsurgical Epididymal Sperm Aspiration (MESA) e. f. Testicular Sperm Aspiration (TESA) Testicular Sperm Extraction (TESE) g. Processing or storage of gametes (sperm & oocyte) and or embryos h. of the patient Pre-implantation Genetic Diagnosis (PGD) i. Pre-implantation Genetic Screening (PGS) j. k. **Endometrial Receptivity Array** I. Time Lapse Imaging

31.

32.

33.

34.

35.

36.

37.

and or embryo

	1. Ye	s 2. No					
38.	If yes	, then please provide the details					
	1. Ye						
	a. Freezing of sperm						
	b. Freezing of oocytes						
	C.	Freezing of zygotes					
	d. Freezing of embryos						
	e. Cryopreservation of ovarian tissue						
	f.	Freezing of Testicular tissue.					
any, f		<b>DECLARATION</b> reby declare that the entries in this form and the additional particulars, if ed herewith are true to the best of my knowledge and belief.					
Date:	·						
		(Signature of Director of the Surrogacy Clinic/Hospital/Institute) Name:					

Designation with Seal: .....

#### FORM 4

## CERTIFICATE OF REGISTRATION Surrogacy Clinic (To be issued in duplicate)

Certificate No.:

1.	In exercise of the powers conferred under Section 12 (1) of the Surrogacy (Regulation) Act, 2021, the Appropriate Authority
	hereby grants registration to the Surrogacy Clinic named below for purposes of carrying out surrogacy or surrogacy procedures as per the aforesaid Act, for a period of five years ending on
	<ul> <li>a). Name and address of the Surrogacy Clinic:</li> <li>b). Name of applicant for registration</li> <li>c). Name of Director of the Surrogacy Clinic:</li> <li>d). Type of institution (Govt. / Private)</li> </ul>
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 5

No...

## Rejection/Suspension Registration/ Renewal of Registration Surrogacy Clinic

In exercise of powers conferred under Section 12 (2) of the Surrogacy (Regulation) Act 2021, the Appropriate Authority hereby rejects the application for grant\* / renewal\* of registration of the Surrogacy Clinic named below for the reasons stated.

Name and address of the Surrogacy Clinic:
Name of applicant who has applied for registration:
Reasons for rejection/ suspension of application for registration/Renewal of registration:
Signature, Name and Designation of the Appropriate Authority  Date:
Place:

\*strike out whichever is not applicable or necessary

# FORM 6 Before The Central Appellate Authority or the State Appellate Authority Appeal No./20......

In the matter of:

Name and Address of Appellant Versus

Name and Address of the Authority Whose Order is Challenged Respondent

Most respectfully showeth:

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

#### Prayer:

That the appellant, therefore prays for the reasons stated above 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.

						Signa	ature of th	ie Appe	llant
Place:									
Date:									
Verification									
l,	do	hereby	verify	that	the	contents	of para		to
are tru	e ar	nd correc	ct to the	e best	of n	ny knowle	dge and b	elief an	d no
part is false and noth	ing i	material	has be	en cor	nceal	ed therein			

**Signature of the Appellant** 

#### FORM 6 (i)

## Proforma/Affidavit Before the Central Appellate Authority Orthe State Appellate Authority

In the matter of:

material has been concealed therefrom.

Name of the Appellant (Appellant)

Versus

Concerned Appropriate Authority (Respondent)

#### **AFFIDAVIT**

I	
	aged
R/o	
	do hereby solemnly declare as under:
1.	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.
2.	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.
Verifi	Deponent ication
conte	ed on this day of (month and year) that the ents of the appeal are true and correct on the basis of my ledge/records/documents/ legal advice received from the counsel and nothing

Deponent

## 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	Particulars	Page No.

**Signature of the Appellant** 

#### **List of Documents**

S. No	Particulars	Page No.

## Form 7 Format for State Boards to furnish the reports to the National Boards

Pursuant to clause (iii) of section 26 of the Act Surrogacy (Regulation) Act, 2021 and Rule of the Surrogacy (Regulation) Act, 2022,

Report for the quarter ended on:
Name of the State/Union Territory Authority
Name of the State/Union Territory:

SI. No.	Items	During the quarter	Total upto this Quarter's end (since inception of the Act)
1	Number of Surrogacy clinic registered in the State/UT as: (Please give details on separate sheet)		
2	Of the number shown in item (1) above, number of Government surrogacy clinics in the State/UT (including Central Government/ State/UT Government/ Zila Parishad/ Municipal):		
3	Of the number shown in item (1) above, number of Private surrogacy clinics in the State/UT (including Central Government/ State/UT Government/ Zila Parishad/ Municipal):		
4	Number of applications for registration of surrogacy clinics has rejected:  (Please give the reason for rejection of application in each case)		
5	Number of renewals of registration of surrogacy clinics:		
6	Number of premises inspected by the Appropriate Authorities or persons authorized by the Appropriate Authorities during the quarter for registration/ renewal of registration/		

	cancellation or suspension of	
	registration/ violations of the	
	Act/Rules	
	(Please give details on separate	
	sheet)	
7	,	
'	<u>'</u>	
	]	
	surrogacy clinic under The Surrogacy	
	(Regulation) Act, 2021 in the	
	State/UT in respect of:	
	(Please give details on a separate	
	sheet)	
8	Action taken to create public	
	awareness against the practice of	
	preconception surrogacy through:	
	(a) Print Media	
	(b) Electronic Media including	
	Radio and TV	
	(c) Social Media	
	(d) Hoarding	
	(e) Other appropriate means	
	(Please give details on separate	
	sheet)	
1	Silect)	
9	Number of nature of the awareness	
9	,	
9	Number of nature of the awareness	
9	Number of nature of the awareness campaigns conducted and results	
9	Number of nature of the awareness campaigns conducted and results flowing therefrom.	
9	Number of nature of the awareness campaigns conducted and results flowing therefrom.  (Please give details including details	
	Number of nature of the awareness campaigns conducted and results flowing therefrom.  (Please give details including details of advertisements/ posters/handbills etc. on separate sheet)	
9	Number of nature of the awareness campaigns conducted and results flowing therefrom.  (Please give details including details of advertisements/ posters/handbills	
	Number of nature of the awareness campaigns conducted and results flowing therefrom. (Please give details including details of advertisements/ posters/handbills etc. on separate sheet)  Details of cases filed against violators of the Act/Rules for:	
	Number of nature of the awareness campaigns conducted and results flowing therefrom.  (Please give details including details of advertisements/ posters/handbills etc. on separate sheet)  Details of cases filed against violators of the Act/Rules for:  (i) Non-registration	
	Number of nature of the awareness campaigns conducted and results flowing therefrom. (Please give details including details of advertisements/ posters/handbills etc. on separate sheet)  Details of cases filed against violators of the Act/Rules for: (i) Non-registration (ii) Non-maintenance of Records	
	Number of nature of the awareness campaigns conducted and results flowing therefrom.  (Please give details including details of advertisements/ posters/handbills etc. on separate sheet)  Details of cases filed against violators of the Act/Rules for:  (i) Non-registration	
	Number of nature of the awareness campaigns conducted and results flowing therefrom.  (Please give details including details of advertisements/ posters/handbills etc. on separate sheet)  Details of cases filed against violators of the Act/Rules for:  (i) Non-registration  (ii) Non-maintenance of Records  (iii) Number of cases decided/ closed.	
	Number of nature of the awareness campaigns conducted and results flowing therefrom.  (Please give details including details of advertisements/ posters/handbills etc. on separate sheet)  Details of cases filed against violators of the Act/Rules for:  (i) Non-registration  (ii) Non-maintenance of Records  (iii) Number of cases decided/ closed.  (iv) Number of surrogacy clinics	
	Number of nature of the awareness campaigns conducted and results flowing therefrom.  (Please give details including details of advertisements/ posters/handbills etc. on separate sheet)  Details of cases filed against violators of the Act/Rules for:  (i) Non-registration  (ii) Non-maintenance of Records  (iii) Number of cases decided/ closed.  (iv) Number of surrogacy clinics sealed/ seized for -	
	Number of nature of the awareness campaigns conducted and results flowing therefrom.  (Please give details including details of advertisements/ posters/handbills etc. on separate sheet)  Details of cases filed against violators of the Act/Rules for:  (i) Non-registration  (ii) Non-maintenance of Records  (iii) Number of cases decided/ closed.  (iv) Number of surrogacy clinics sealed/ seized for -  (a) non-registration of clinic/	
	Number of nature of the awareness campaigns conducted and results flowing therefrom.  (Please give details including details of advertisements/ posters/handbills etc. on separate sheet)  Details of cases filed against violators of the Act/Rules for:  (i) Non-registration  (ii) Non-maintenance of Records  (iii) Number of cases decided/ closed.  (iv) Number of surrogacy clinics sealed/ seized for -  (a) non-registration of clinic/ center	
	Number of nature of the awareness campaigns conducted and results flowing therefrom.  (Please give details including details of advertisements/ posters/handbills etc. on separate sheet)  Details of cases filed against violators of the Act/Rules for:  (i) Non-registration  (ii) Non-maintenance of Records  (iii) Number of cases decided/ closed.  (iv) Number of surrogacy clinics sealed/ seized for -  (a) non-registration of clinic/ center  (b) other violations of the	
	Number of nature of the awareness campaigns conducted and results flowing therefrom.  (Please give details including details of advertisements/ posters/handbills etc. on separate sheet)  Details of cases filed against violators of the Act/Rules for:  (i) Non-registration  (ii) Non-maintenance of Records  (iii) Number of cases decided/ closed.  (iv) Number of surrogacy clinics sealed/ seized for -  (a) non-registration of clinic/ center  (b) other violations of the Act/Rules	
	Number of nature of the awareness campaigns conducted and results flowing therefrom.  (Please give details including details of advertisements/ posters/handbills etc. on separate sheet)  Details of cases filed against violators of the Act/Rules for:  (i) Non-registration  (ii) Non-maintenance of Records  (iii) Number of cases decided/ closed.  (iv) Number of surrogacy clinics sealed/ seized for -  (a) non-registration of clinic/ center  (b) other violations of the	

11 Action taken inclusive of search and seizure of surrogacy clinics,	
seizure of surrogacy clinics,	
documents or records etc. against	
bodies/person operating without a	
valid certificate of registration under	
the Act. (Please give details on	
separate sheet)	
12 Information/Report on survey of	
surrogacy clinic to unearth	
violation(s) of provisions of the	
Act/Rules.	
(Please give details on separate	
sheet)	
13 Number of complaints received by	
the Appropriate Authorities under the	
Act and details of action taken	
pursuant thereto.	
(Please give details on separate	
sheet)	
14 Number of RTI received by the	
Appropriate Authorities under the Act	
and details of action taken pursuant	
thereto.	
(Please give details on separate	
sheet)	
,	
15 Number of complaints filed in courts	
in the State/UT by Appropriate	
Authorities/ others).	
(Please give details on separate	
sheet)	
16 Details of action taken on the	
information/ report received from the	
patient or other source regarding	
surrogacy.	
(Please give details on separate	
sheet)	
17 Details of incidence coming to the	
notice of the State/UT regarding	
surrogacy to bodies not registered	
under the Act and action take	
thereon.	
(Please give details on separate	
sheet)	

18	i. Dated of the meetings of the State	
	Supervisory Board constituted	
	under section 29(1) of the ACT (at	
	least once in 4 months).	
	ii. Dates of the meetings of the	
	States level Multimember	
	Appropriate Authority appointed at	
	the State/UT level under section	
	35(2) (a) of the Act.	
	iii. Dates of the meetings of each	
	Advisory Committee (the	
	intervening period between	
	meetings of Advisory Committees	
	should not exceed 60 days).	
	(Please give details of the	
	meetings of each and every	
	Advisory Committee functioning at	
	State, District and Sub-District	
	level on separate sheet)	
19	Action taken to publish list of	
	members of the State Supervisory	
	Board, Appropriate Authorities and	
	Advisory Committees through:	
	(a) Print Media	
	(b) Social Media	
	(c) Electronic Media Hoardings	
	(d) Any other appropriate means	
	(Please give details on separate	
	sheet)	

Certified that all bodies/persons performing surrogacy procedure/services/ activities in my area of jurisdiction have been registered under the Act and prosecution has been launched against those who have not got themselves registered.

Date:	Name:
Place:	Designation:
	Signature:
	Seal·

#### (For and on behalf of State Government/U.T. Administration)

#### FORM 8

No...

## Cancellation/Suspension of Registration Surrogacy Clinic

In exercise of powers conferred under Section 18 of the Surrogacy (Regulation) Act 2021, the Appropriate Authority hereby suspends the registration of the Surrogacy Clinic named below for the reasons stated.

Name and address of the Surrogacy Clinic:
Name of applicant who has applied for registration:
Reasons for cancellation of registration:
Signature, Name and Designation of the Appropriate Authority
Date:
Place:
OLAL

\*strike out whichever is not applicable or necessary

#### FORM 9:

#### The manner of giving notice by a person/social organization to the Appropriate Authority

I/ We(Name/ Address/Details) Intend to make a complaint to the court regarding (Matter to be mentioned in brief)
Details of the person/clinic/authority against whom I/we are making the complaint.
I certify that I am making this complaint on (day and date) at
(city/pin code/address) at least fifteen days in advance to approaching the court in respect to this matter.

#### **FORM 10**

#### **Application Form for Intending Couple for availing Surrogacy**

#### 1. Basic Information

1.1	Details	of Inter	nded	Father:
-----	---------	----------	------	---------

- 1. Name:
- Surname:
- 3. DOB:
- 4. Blood Group:
- 5. Age in years:
- 6. Sex: Male/ Female
- 7. Nationality:
- 8. Occupation:
- 9. Marital Status: Married/ Divorced /Widow.
- 10. Address:
  - i) Present:
  - ii) Permanent
- 11. Telephone/Mob. No.
- 12. Email:
- 13. Medical History: (Please specify the condition if any)

#### 1.2 Details of the Intended Mother:

- 1. Name:
- 2. Surname
- 3. DOB:
- 4. Blood Group:
- 5. Age in years
- 6. Sex:
- 7. Male Female
- 8. Nationality:
- 9. Occupation:
- 10. Marital Status: Married/ Divorced /Widow.
- 11. Address:
  - i) Present:
  - ii) Permanent
- 12. Telephone/Mob. No.
- 13. Email:
- 14. Do you have a History of Miscarriages?
- 15. If yes Number: .....
- 16. Any other Medical History: (Please specify the condition if any)
- 1.3 Duration of Marriage in years
- 1.4 Trying to conceive since (years)

1.5	Do y	ou have any child before?
1.6	•	s, Does the child suffer from any abnormality or life-threatening lition.
1.7	Plea	se describe
1.8	Have	e you tried any other ART procedure before availing Surrogacy?
1.9	If yes	s, please specify
	a)	Specify the procedure
	b)	
	c)	How many failed attempts.
	d)	Any medical complications of the procedures if any
1.10	Brief	ly describe the reason for availing surrogacy
Decla	aration	1
I here	•	clare that the above statements are true to the best of my knowledge
Date:		Signature of the Intended father
Dlaco		

#### **Signature of the Intended Mother**

#### **Duly attested Documents required for applying**

- 1. Proof of marriage / Marriage Certificate
- 2. Proof of age/ Birth certificate/10<sup>th</sup> certificate/ or any equivalent.
- 3. Proof of divorce/Divorce Certificate
- 4. Proof of Medical record/condition for availing surrogacy
- 5. Proof of abnormality/ life threatening condition in case of previous abnormal child

#### FORM 10A

#### **Application Form for Indian Women** (Widow/Divorced)

Name of the applicant

1.

	Signature of the Applicant Intended Mother
Date:	
I here	eby declare that the above statements are true to the best of my knowledge pelief.
Decla	aration
	y doconibo the reason for availing earlogacy
Briefl	y describe the reason for availing surrogacy
20.	Any medical complications of the procedures if any
19.	How many failed attempts.
18.	Did the procedure result in pregnancy or birth or failed attempt?
17.	If yes, Specify the procedure
16.	condition, please describe
15.	If yes, Does the child suffer from any abnormality or life-threatening
14.	Do you have any child before?
13.	Medical History if any
12.	Date of Divorce in case the applicant: is divorced enclose attested copy of Final Divorce Certificate.
	copy of husband death certificate
10. 11.	Profession or Occupation  Date of Death of Husband in case the applicant is a widow, enclose attested
9. 10.	Permanent Address  Profession or Occupation
8.	Residential Address
7.	Marital Status: 1. Single 2. Married 3. Divorced 4. Window
6.	Nationality
5.	Father's/Mother' s/Spouse's name
4.	Age in yrs (enclose attested copy age proof/birth certificate)
2. 3.	Blood Group
2.	Surname

**Duly attested Documents required for applying**Proof of age/ Birth certificate/10<sup>th</sup> certificate/ or any equivalent Proof of Divorce / Death Certificate

#### **FORM 11**

#### Certificate of Essentiality for Intending Couple

Certificate is granted to that Mrs.:	resident of
of	
(Name & address of Clinic/Hospital) for infertili have not been to conceive despite of various tre	ity since(dd/mm/yy) and
I hereby certify that couple requires to undergo treatment which is essential for their treatment o	
DECLARATION TO BE SIGNED BY	THE GOVT. SERVANT
I hereby declare that the statements in this app best of my knowledge	
	Signature & Seal
Date:	Name of the Sanctioning Officer Appropriate Authority
Dlace	

#### **FORM 12**

#### **Certificate of Medical Indication for Intending Couple**

Mrs		• • • • • • • • • • • • • • • • • • • •		.wife	of	Mr		
have	been	undergoing	treatment ofof	infertility	/ und	er the (Name	supervision of treating	of Dr. doctor)
(Medi treatn	cal Conent for	ndition) and r	ned the coupsuf require to unde	fers fron rgo surre	n ogacy	proced	ure as an ad	vanced
Subili	illed to	me in the apo		DATION				
l he	ereby de	eclare that the	e statements in best of my kno		ificate		and correct t	o the
Place								

Signature & Seal

Name of the Medical Office of the District Board

Seal of the court

#### **FORM 13**

Order of Parentage/ Birth Affidavit

F	ile No	
Details of Infant Name of the Child: Sex: DOB: Birth Place: State: (Name of the Institution/Hos delivered): Address:	City: Country: spital/Nursing Home	e/Surrogacy Clinic, where the child is
Details of Birth Mother/ Su Name of the Surrogate Moth DOB: Birth Place: Address: Aadhar Number:	_	
Details of the Intended Par Name of the Father DOB: Birth place Residential Address Aadhar Number	rents	Name of the Mother DOB: Birth place Residential Address Aadhar Number
Act Article Nodesignation	of the of the that an order of pa e above named to	(Name of the(Name of the(Name of the official) Court of(Name or arentage was made by the said cour be the parent(s) of the child whose
Date: Place:		

Page **53** of **69** 

#### **Acknowledgement**

We understand that signing this Acknowledgment of Parentage will establish parentage of our child with the same force and effect as an Order of Parentage entered after a court hearing including an obligation to provide support for our child except that, only if this Acknowledgment of Parentage is filed with the Registrar where the birth certificate is filed, will the Acknowledgment of Parentage have such force and effect with respect to inheritance rights. We have received written and oral notice of our legal rights (including the timeframes to withdraw), responsibilities, alternatives and the consequences of signing the Acknowledgment of Parentage, and we understand what the notice states. A copy of the written notice has been provided to us.

**Signed Intended Mother** 

Signed Intended Father

#### FORM 13 (A)

	CE	STATE OF	<b>'</b> Н		
Certificate No			File No Registration		
Name of the Child Sex: DOB: Birth Place:	State:	City:	Country:		
(Name of the Institu Address:	ution/Hospita	l/Nursing Home/Surro	ogacy Clinic):		
Father Name: DOB: Birth place: Residential Addres Aadhar Number: I hereby acknowled above		the genetic or intende	Mother Name:  DOB: Birth place: Residential Address: Aadhar Number: ed parent of the child named		
Signature of the Intended Mother			Signature of Intended Father		
	F	For Official Use Only			
This is a true certi	ification of th	onon	ereby filed with the registrar cts as recorded in the office of f Authority)		
Place:			State Registrar		

Query: Whether name of the surrogate mother will appear on the certificate or not.

#### **FORM -14**

, · ~	PTITE.	cate	$\sim$

Certificate of Medical & Psychological Fitness of Surrogate Mother
--

Dr(name of Doctor),
practicing at( Name & address of
hereby certify that I have physically and psychologically examined
Smt./Kumariyears
and resident ofintended to act as a Surrogate
mother for Mrs./Ms& Mr.
(Name of the intended couple/
woman) resident ofand
cannot discover that she has any disease, communicable of otherwise
constitutional affection or bodily infirmity. Based on the examination I found her
Medically, Mentally and Physically fit to undergo surrogacy procedures.
hereby also certify that She has been vaccinated for the COVID 19 disease.
The certificate is valid from to
Name & Signature with seal
of the Registered Medical Practitioner/ Civil Surgeon
Date:
Place:

#### **FORM 15**

#### **Consent Form for Withdrawal**

I
Mrs. /Ms. and Mr for the reasons stated below.
Specific Reasons for withdrawing
Signature of the Surrogate Mother
Signature of Spouse (husband, if any)
Endorsement by the Surrogacy Clinic
I / we have personally explained to Mrs. /Ms
Name, address and signature of the Witness from the clinic
Name and signature of the Doctor
Name and address of the Surrogacy clinic
Signature of the Surrogate Mother
Signature of Spouse (if available)
Dated
* Strike of which is not applicable

Page **57** of **69** 

#### **FORM 16**

### Format for Making Complaint to Appropriate Authority against A Surrogacy Clinic

#### Instructions:

- 1. Please submit the complete form.
- 2. Ensure all signatures are authorized and additional documentation is provided.
- 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 First Name

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 (YYYY-MM-DD):

#### Relationship to the Patient is

- 1. Patient (Self)
- 2. Legal Representative
- 3. Relative /Family member

4. 5.	Anonymous Others					
Patie	nt Informatio	n (If different from	above)			
Name	:					
Addre	ess line 1:					
Addre	ess line 2:					
City:		Postal code:	Conta	ct Numbe	r:	Email:
Date of	of birth (YYYY	-MM-DD):				
Status 1. Aliv	s of the patien	t: 2. Deceased				
Detail	ls of Complai	nt Filed Against (R	Respon	dent):		
Name	of the person	/organization:				
Addre	ess line 1:					
Addre	ess line 2:					
City:		Postal code:		Contact	Number:	
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 concer organization	ned or to any other
Name of the person to whom complaint was reported	
Contact Details:	
Email:	
Address:	
Date of reporting the complaint:	
Action taken	
	nplainant'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 17**

#### Certificate No.

#### The Appropriate Authority **Eligibility Certificate**

(Intending Couple)

			-		intending	
					ge	
					age	_
					der the provisi er. Under the sa	
the coupl	e is e	ligible to		rogacy Pro	ocedure for the	
manayem	ent or in	ieruiity subj	ect to the term	is a conditi	J115	
The certific	cate is v	alid from	to			
Date:						
Sign& Sea	al:					
Appropriat	e Autho	rity:				
Place:						

#### Terms:

Thin

- The Intended couple should be duly married. 1.
- 2. "Intending woman" means an Indian woman who is a widow or divorcee between the age of 35 to 45 years and who intends to avail the surrogacy (The lower age limit of "intending women" needs to be below than 35 years, as current age limit necessitates younger widow/divorcee to wait up to 35 years for their right of motherhood. Therefore, the lower age limit for "indenting women" should be same as female partner of "indenting couple" i.e., 23 years).
- 3. The Surrogacy services shall be available to a woman above the age of twenty-three years and below the age of fifty years and to a man above the age of twenty-six years and below the age of fifty-five years; (The legal age of marriage is 21 years and infertility is defined as inability to conceive within one year of unprotected intercourse. The lower limit of female age as 23 years remains questionable, as sometimes the absolute indication of surrogacy can be uterine factor like congenital absence of uterus, wherein the female can only conceive with the help of surrogacy and her right to conceive can't be withheld for extra 2 years beyond the age of 21. Therefore: The lower limit for female partner of "intending couple" should be 21 years).

- 4. The intending couple should not have had any surviving child biologically or through adoption or surrogacy earlier.
- 5. Duration of Infertility: Trying to conceive for more than 1 year of unprotected coitus
- 6. The couple has a medically necessitating condition.
- 7. Upon production of Marriage certificate.

#### **FORM 17 A**

#### Certificate No.

## The Appropriate Authority Eligibility Certificate

(Intending Women)

This is to certify that Msstatus (widow/ divorced) residing at	•	
under the provision of The Surrogacy (Regulation) Act, Under the said certificate is eligible to undergo Surrogac terms & conditions*.	2021 & Rules	there under.
The certificate is valid from to		
Date:		
Place:		
		Sign & Seal: e Authority:

#### Terms:

- 1. Surrogacy services shall be available to a woman above the age of twenty-three years and below the age of fifty years. (**The lower age limit of** "intending women" needs to be below than 35 years, as current age limit necessitates younger widow/divorcee to wait up to 35 years for their right of motherhood. Therefore, the lower age limit for "indenting women" should be same as female partner of "indenting couple" i.e. 23 years).
- Surrogacy services shall be available to Indian woman who is a widow or divorcee between the age of 35 to 45 year or a couple who have a medical indication necessitating gestational surrogacy and who intend to become parents through surrogacy; Indian woman who is a widow or divorcee between the age of 35 to 45 year or a couple who have a medical indication necessitating gestational surrogacy and who intend to become parents through surrogacy
- **3.** Upon Proof of Divorce / Death Certificate

**Appropriate Authority** 

#### **FORM 17 B**

Certificate No.

## The Appropriate Authority Eligibility Certificate

(SURROGATE MOTHER)

This is to certify that	Ms	age
residing at		under the provision of
	•	here under. Under the said HER' subject to the terms &
Relationship with the intend	ed couple/woman	
The certificate is valid from	to	
Date:		
Place:		
		Sign & Seal

#### **Terms & Conditions**

- 1. Surrogate mother shall be an ever-Married women having a child of her own and between the age of 25 to 35 years on the day of implantation.
- 2. Husband consent required.
- 3. The surrogate mother shall not help in surrogacy by donating her egg.
- 4. No woman shall act as a surrogate mother more than once in her lifetime.
- 5. Not more than 3 time for the same couple when the first embryo transfer has failed in a surrogate mother, at most two more successful embryo transfers for the same couple.

#### Form 18

Witten Consent for Surrogate for Abor	tion/Medical Termin	ation of Pregnancy
I Mother)	wife	of
(Name of Husband) of age	rears acting as a some some some some some some some some	surrogate mother of (Name of the to termination of pregnancy at
(Name of Clinic/Hospital/Nursing home) visituated at/Nursing home) upon the advice of the dome.	where the pregnancy(Address	is to be terminated) of Clinic / Hospital
Name & Signature of the Surrogate Mo	ther	
Name & Signature of the Intended Cou	ple/ Woman	
Name & Signature of the Doctor		
Name, address and signature of the Wi of Surrogacy clinic/hospital/Nursing Ho where pregnancy is terminated		
Place:		
Date:		

#### **Endorsement by the Surrogacy Clinic**

I / we have personally explained to Mrs
Signed:
Signature of the Surrogate Mother:
Signature of the Doctor:
Name, Address and Signature: of the Witness from the Surrogacy clinic

#### **Terms & Conditions for Abortion**

- 1. Up to 20 weeks upon advice of one doctor.
- 2. Between 20 24 weeks. Two doctors for some categories of pregnant surrogate mother. [For E.g.: In case of grave injury to her physical or mental health or severe physical or mental abnormality of the foetus].
- 3. More than 24 weeks Medical Board in case of substantial foetal abnormality.
- 4. Anytime during pregnancy- one doctor if abortion is immediately necessary to save the life of the surrogate mother.

## Form 19 Screening of the Surrogate

#### Date of Screening Surrogate:

#### **Basic Information**

- 1. Name & Identification number (Surrogate ID)
- 2. Aadhar number
- 3. Age / Date of birth
- 4. Place of birth
- 5. Marital status
- 6. Education
- 7. Occupation
- 8. Monthly income
- 9. Religion
- 10. Address
- 11. Telephone
- 12. Email

#### **History**

- 13. Obstetric history
  - i) Number of deliveries
  - ii) Number of living children
  - iii) Number of abortions
  - iv) Any History of still birth/Bad obstetric history
  - v) Any complication in previous pregnancy like hyperemesis, preeclampsia, gestational diabetes
  - vi) 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 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:
  - a. Hb
  - b. Total RBC count
  - c. Total WBC count
  - d. Differential WBC count

- e. Platelet count
- f. Peripheral smear
- 23. Random blood sugar (HbA1C)
- 24. FBS, PPBS
- 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
- 33. Sexually transmitted diseases

#### **Features**

- 34. Height
- 35. Weight
- 36. BMI

#### **Details Physical Examination**

- 37. Pulse
- 38. Blood pressure
- 39. Temperature
- 40. Pallor, Oedema
- 41. Respiratory system
- 42. Cardiovascular system
- 43. Per abdominal examination (PS/PV)
- 44. Ultrasound between day 2-day 5
- 45. Ultrasound between day 10-15 to check for Endometrial thickness and blood flow

Other Systems:	
-	

#### Footnotes:

- 1. To be carried out within three months prior to embryo transfer All blood investigation will hold a validity of six months and will have to be repeated if duration since last investigation is more than six months.
- 2. Any additional test carried out on the basis of the history and examination of Surrogate.

	Name
	Signature
Date:	