

## **Frequently Asked Questions on ART (Regulation) Act, 2021**

### **(A) Eligibility Criteria for availing ART services in India**

**1. What is the age criteria for availing IVF treatment in India?**

Reply: The age criteria for woman and man to avail IVF treatment in India is between 21 to 50 years and 21 to 55 years respectively. (Section 21 (g) of ART Act, 2021)

**2. Can the age criteria be relaxed for the commissioning couple under the ART Act, 2021?**

Reply: No. There is no provision to relax the age criteria for the commissioning couple under the ART Act, 2021.

**3. Whether unmarried woman is allowed to avail ART services?**

Reply: Yes. Any woman who is above the age of 21 years and below the age of 50 years can avail ART services.

**4. Can foreigners avail IVF treatment in India?**

Reply: Yes. Foreigners can avail IVF treatment in India subject to the fulfillment of the eligibility criteria prescribed under the Assisted Reproductive Technology (Regulation) Act, 2021 and the Rules made there under.

**5. Can Single man avail IVF treatment in India?**

Reply: No, single man cannot avail IVF treatment in India.

**6. What is the age limit for sperm donor and egg donor?**

Reply: Any man between the age of 21-55 years can donate sperms and any woman between the age of 23-35 years can donate eggs (oocytes). (Section 27(2) (a) & 2 (b) of ART Act, 2021)

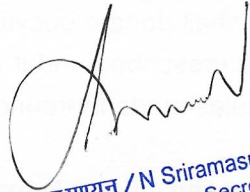
**7. Can a couple or a woman undergo IVF treatment for second child if they already have a surviving child?**

Reply: Yes. There is no bar under the ART Act for a couple or a woman to undergo ART or IVF treatment for a second child.

**8. Who is considered a 'commissioning couple' under the Act?**

Reply: A commissioning couple is an infertile married couple who approaches an ART clinic or bank for ART services.

### **(B) Gamete donation & donor regulations**

  
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**9. Who is a gamete donor?**

Reply: Gamete donor means a person who provides sperm or oocyte(eggs) with the objective of enabling an infertile couple or woman to have a child. *(Section 2 (1) (h) of ART Act, 2021)*

**10. Can sperm donor donate sperm to more than one commissioning couple?**

Reply: No. Sperm donor cannot donate sperm to more than one commissioning couple. *(Section 27 (3) of ART Act, 2021)*

**11. Can oocytes of one oocyte donor be shared with more than one commissioning couple?**

Reply: No. Oocytes of a donor cannot be shared with more than one commissioning couple *(Section 27 (3) of ART Act, 2021)*

**12. How many times a woman can donate eggs (oocytes)?**

Reply: A woman can donate eggs (oocytes) only once in her lifetime subject to fulfilment of the eligibility criteria prescribed under the Assisted Reproductive Technology (Regulation) Act, 2021 and the rules made there under. *(Section 27 (4) of ART Act, 2021)*

**13. How many oocytes can be collected from an oocyte donor?**

Reply: For retrieving oocytes from the donor, clinics shall make efforts to retrieve not more than seven oocytes during one cycle. However, the clinics shall retrieve all formed follicles. *(Para 2 of ART Regulations 2023 dated 5th April 2023)*

**14. Can the oocyte(egg) donor/sperm donor be financially compensated?**

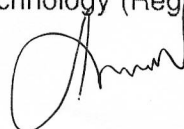
Reply: The sale and purchase of gametes /embryos is a punishable offence as mentioned in Section 33 (1) (b) of the Assisted Reproductive Technology (Regulation) Act, 2021.

**15. Can a known person /friend or relative of a couple donate eggs to commissioning couple?**

Reply: A known person /friend or relative of the couple can donate eggs but only after the screening and registration of the egg donor by a registered ART bank. The egg donor shall donate oocytes only once in her life subject to fulfillment of all the eligibility criteria prescribed under the Assisted Reproductive Technology (Regulation) Act, 2021 and Rules made thereunder.

**16. Can the couple bring their own egg donor?**

Reply: Yes, the couple can bring their own egg donor and the donor should satisfy the prescribed criteria under the Assisted Reproductive Technology (Regulation) Act, 2021 and the Rules made thereunder.



**17. If a couple wants to donate their unused eggs to another couple or family member, can it be done?**

Reply: No. All unused eggs shall be preserved by the banks for use on the same recipient.

**18. Can ART Bank retrieve the oocytes of a donor?**

Reply: No. The surgical retrieval of gametes (which includes ovum pickup) shall be done by the registered Level 2 ART Clinic.

**19. Can a single woman who is unmarried undergo IVF or IUI treatments with donor sperm?**

Reply: Yes. Any woman above the age of twenty-one years and below the age of fifty years may undergo IVF or IUI treatments with donor sperm subject to the fulfillment of the other eligibility criteria prescribed under the Assisted Reproductive Technology (Regulation) Act, 2021 and the rules made thereunder.

**20. Are there any restrictions on the use of donor gametes?**

Reply: Yes. Donor gametes must be obtained from registered ART banks and the donors must be medically tested for specified diseases. The gametes of a donor shall be used for one commissioning couple subject to fulfillment of other criteria prescribed under section 27 of the ART Act and rules made thereunder.

**21. What are the diseases for which sperm & oocyte donors are tested?**

Reply: The sperm or oocyte donor shall be tested for the following communicable diseases, namely:- (a) Human immunodeficiency virus (HIV), types 1 and 2; (b) Hepatitis B virus (HBV); (c) Hepatitis C virus (HCV); (d) Treponema pallidum (syphilis) through VDRL. *(Rule 10 of ART Rules, 2022)*

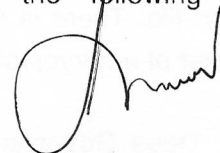
### **(C) Insurance coverage**

**22. Who are covered for insurance under the ART Act and what is the period of insurance coverage?**

Reply: The ART Act provides for insurance coverage for a period of 12 months to be purchased by the commissioning couple or woman in favour of the oocyte donor from an insurance company or an agent recognized by the IRDAI for an amount, which is sufficient enough to cover all expenses for all complications arising due to oocyte retrieval. *[Section 22 (1) (b) ART Act].*

**23. What are the insurance products available for a oocyte donor?**

Reply: The detailed list of products (health and life cover) for insurance coverage of oocyte donor as endorsed by IRDAI are available on the following link



<https://artsurrogacy.gov.in/public/fornt/assets/images/Notifications/rules/List%20of%20Insurance%20Products.pdf>

**24. Is there any provision for insurance coverage for sperm donor under the ART Act?**

Reply: No. There is no provision of insurance coverage for sperm donor.

**(D) Transfer of embryos and gametes**

**25. Can the frozen oocytes/sperms/embryos be transferred from one ART clinic to another?**

Reply: Yes. Frozen oocytes/sperms/embryos can be transferred from one ART clinic to another clinic within or outside India with the permission of the National Board in accordance with section 29 of the ART (Regulation) Act,2021 and Rules made there under.

**26. What are the documents required for transfer of embryos/ gametes?**

Reply: The requisite documents for applying for permission for transfer of embryos/ gametes are given as under:

1. Application form (Form 16)
2. Affidavit from the applicant for transfer of frozen embryos/gametes (Form 17-20).
3. Affidavit of the clinic holding the frozen embryos/gametes (Form 21-22).
4. Affidavit of the clinic receiving the frozen embryos/gametes (Form 23-24).

The detailed forms regarding **transfer of embryos/ gametes** are prescribed under Rule 19 of the ART (Regulation) Rules, 2023 notified on 24.02.2023 which are available on the following link [https://artsurrogacy.gov.in/public/fornt/assets/images/permission\\_for\\_transfer%20of\\_embryos\\_gametes/assisted-Reproductive-Technology-Amendment-Rules-2023.pdf](https://artsurrogacy.gov.in/public/fornt/assets/images/permission_for_transfer%20of_embryos_gametes/assisted-Reproductive-Technology-Amendment-Rules-2023.pdf).

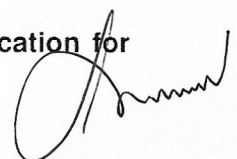
**27. Is import of human embryo or human gametes allowed?**

Reply: No. As per the Assisted Reproductive Technology (Regulation) Act,2021 and the Surrogacy (Regulation) Act,2021 the import of human embryos/gametes is strictly prohibited. It is a punishable offence and can result in imprisonment and fines as specified under the Act. (*Section 33 (1) (c) of ART Act , 2021 and 38 (1) (f) of Surrogacy Act,2021*)

**28. Whether there is any need to engage a lawyer for applying for permission for transfer of embryos/gametes from one clinic to another clinic.**

Reply: No. There is no requirement of engaging a lawyer to apply for permission for transfer of embryos/gametes from one clinic to another clinic.

**29. Does Government of India charge any fees for processing application for**



**transfer of embryos/gametes within or outside India.**

Reply: No. There is no fee for applying/ processing of the application for transfer of embryos/gametes within or outside India.

**(E) Ethical Practices & safeguards**

**30. Can ART clinics perform procedures without written consent?**

Reply: No. Written informed consent from all parties seeking ART is mandatory before performing any procedures.

**31. Is sex selection allowed in ART?**

Reply: Any act to determine or increase the probability of the sex of the child to be born through ART is prohibited.

**33. Can a clinic mix semen sample of two or more individual for ART Procedure?**

Reply: No. A clinic shall never mix semen from two individuals for the procedures specified under ART Act. Mixing of semen sample of two individuals is a punishable offence.

**34. Can a married woman undergo IVF or IUI treatment without the consent of her husband.**

Reply: No. A married woman cannot undergo IVF or IUI treatment without the consent of her husband. The written informed consent from all parties seeking ART is mandatory before performing any procedures.

**(F) Rights and Welfare**

**35. Does a child born through ART/Surrogacy has same rights as that of a biological child?**

Reply: Yes. A child born through ART/Surrogacy has same rights as that of a biological child and is entitled to all the rights and privileges available to a natural child.

**36. Can donors retain parental rights over the child born through ART?**

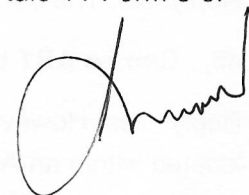
Reply: No. Donors must relinquish all parental rights over the child born from their gametes.

**37. Can a commissioning couple withdraw consent for ART procedures?**

Reply: Yes. Either party can withdraw consent at any time before the transfer of embryos or gametes to the woman's uterus.

**38. How can a complaint be made against a clinic or a bank?**

Reply: The format for making complaint against a clinic is given under Rule 11 Form 5 of the ART Rules, 2022.



**39. Can a couple use their own frozen embryos second time for the purpose of their own IVF.**

Reply: Yes. There is no prohibition under the ART Act, 2021 for use of frozen embryos second time for the purpose of own IVF treatment.

**(G) Duties of ART Clinics and Banks**

**40. What duties do ART clinics have regarding patient counseling?**

Reply: Clinics must provide professional counseling about the implications and chances of success of ART procedures, including risks and costs.

**41. How is confidentiality maintained in ART procedures?**

Reply: ART clinics and banks must keep patient information confidential and only disclose it to the National Registry or in a medical emergency or by court order. (*Section 21 (e) of ART Act, 2021*)

**42. Can an ART Clinic counsel a legally married woman below the age of 21 years for natural methods of conception?**

Reply: There is no bar under the Assisted Reproductive Technology (Regulation) Act, 2021 for such counselling. However, the ART procedures can only be performed on woman of age ranging from 21 years to 50 years.

**(H) Level 1 & level 2 clinics**

**43. What are the types of ART clinic?**

Reply: There are two levels of ART clinic:

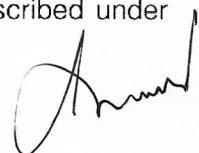
- (i) Level 1 ART Clinics, where only intrauterine insemination (IUI) procedure is carried out as part of treatment;
- (ii) Level 2 ART clinics, where the procedures that attempt to obtain a pregnancy are carried out by any or all of the following, namely:- (a) surgical retrieval of gametes; (b) handling the oocyte outside the human body; (c) use sperms for fertilization of oocytes; (d) transfer of the embryo into the reproductive system of a woman; (e) carryout storage of gametes or embryos or perform any kind of procedure or technique involving gametes or embryos.

**44. Can a Level 1 ART clinic do oocyte retrieval?**

Reply: No. The oocyte retrieval must be done at a registered Level 2 ART clinic only.

**45. Can an ART bank be co-located with an ART Level-1 or Level-2 facility?**

Reply: Yes. However separate registration is required for the ART Bank, even if it is co-located within an ART Level 1 or Level 2 facility. The Clinic and bank must also fulfill the requirements of staff, equipments and other procedural requirements prescribed under



the ART Act and ART Rules.

**46. Does change in the address of a registered clinic/bank require re-registration of the clinic/bank by the State/UT Authority?**

Reply: Yes. For any change in the address of a registered clinic/bank the complete process of re-registration of the new premises must be carried out including inspection of the premises along with payment of registration fee as prescribed under Rule 7 of the ART (Rules, 2022) and Rule 10 (2) of Surrogacy Rules, 2022.

**47. Can a voluntary egg donor donate eggs to the Level 2 ART clinics?**

Reply: Yes. The voluntary egg donors can undergo procedure for egg retrieval at registered Level 2 ART clinic. However, the registration and screening of egg donors shall only be done by a registered ART bank. The donor should satisfy the prescribed criteria under the Assisted Reproductive Technology (Regulation) Act, 2021 and the Rules made thereunder.

**48. Can a Level 2 ART Clinic be in a hospital setup?**

Reply: Yes, subject to the fulfillment of all the requisite facilities and the trained manpower for carrying out the procedures related to the assisted reproductive technology. Please refer Schedule 1 (Part 1 and 2) of Rule 4 and 5 of the Assisted Reproductive Technology (Regulation) Rules, 2022.

**49. Can a Level 2 ART clinic stimulate woman/oocyte donor and send them to another Level 2 ART clinic for ovum pickup?**

Reply: No. The stimulation and retrieval must be completed at the same clinic.

**(I) Staff requirement in clinics and banks**

**50. What is the Staff requirement of ART clinic & ART Bank?**

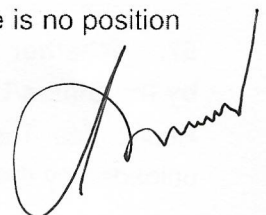
Reply: The staff requirement at ART clinic and bank are as under:

- (i) ART Level 1 clinic: Minimum 01 gynecologist
- (ii) ART clinic Level 2 shall have a minimum of one gynecologist, one anesthetist, one embryologist and one counsellor. Additional staff at the level of Director and Andrologist may be employed by the ART Level 2 clinics.
- (iii) The ART bank shall have a minimum of one Registered Medical Practitioner.

The details of staff requirement, qualifications & experience of the staff in the ART clinics is specified under part 1 Schedule 1 of the ART Rules, 2022.

**51. Can a Gynaecologist in a Level 2 ART clinic work as a program coordinator or Director apart from their role as a Gynaecologist?**

Reply: There are only two levels of ART clinics, Level 1 and Level 2. There is no position



of program coordinator in the ART Rules, 2022. A gynaecologist in a Level 2 ART clinic can perform the role of Director as well, without compromising their duties as a gynaecologist as specified under the ART Act and Surrogacy Act and Rules made thereunder.

**52. Can a Urologist working part-time in an ART Clinic be treated as a regular member in place of an Andrologist?**

Reply: As per the amendment in ART Rules, 2022 notified on 11th July 2023, an Andrologist in a clinic or bank must have specific qualifications such as MCh or DNB in Urology, MS in General Surgery, or FNB/MCH/DM in reproductive medicine with a minimum of 2 years' experience and hands-on experience of at least 15 surgical sperm retrieval procedures.

**(J) Registration & Fee**

**53. Is registration mandatory for ART clinics and banks?**

Reply: Yes. No person can establish or operate an ART clinic or bank without registration under the Act.

**54. What is the validity period of the registration for ART clinics and banks?**

Reply: The registration is valid for five years and can be renewed for an additional five years.

**55. Is there any registration fee to apply for licence of ART clinic, ART Bank and Surrogacy Clinic?**

Reply: Yes. Every application for registration shall be accompanied with a fee prescribed under Rule 7 of the ART (Regulation) Rules, 2022 and Rule 10 (2) of Surrogacy (Regulation) Rules, 2022 for all the private establishments. Every application for registration shall be accompanied with a fee of:

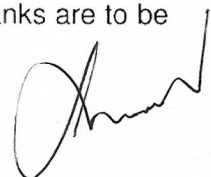
- i. Level 1 ART clinic-Rupees 50,000
- ii. Level 2 ART clinic: Rupees 2,00,000
- iii. ART bank: Rupees 50,000.
- iv. Surrogacy Clinic: Rupees 2,00,000

**56. Can the registration fee be refunded?**

Reply: No. The registration fees once paid shall not be refunded provided that if an application for registration of any ART clinic or ART bank or 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 clinic/bank.

**57. Whether registration certificates issued to clinics/banks are to be uploaded by the States/UTs.**

Reply: Yes. The registration certificate/rejection orders issued to clinics/banks are to be uploaded by the concerned States/UT directly on the National Registry.





**58. Is there any relaxation for government ART clinics to pay registration fees?**

Reply: Yes. Establishments (clinics/ banks) run by the institute under control of Government are exempted from paying registration fees as per proviso under Rule 7 of ART Rules, 2022.

**59. Do Level-1 and Level-2 ART clinics require separate registrations?**

Reply: Yes. Separate registrations are required for performing functions as Level 1 or Level 2 ART clinics.

**60. Do satellite centres of ART clinics in neighbouring states required to be registered?**

Reply: Yes. Satellite centres should be registered either as Level 1 or Level 2 clinics based on the application submitted by the concerned ART clinic to the State/UT Appropriate Authority.

**61. Are there written instructions regarding the utilization of registration fees collected from ART clinics/banks & Surrogacy clinics?**

Reply: Yes. The registration fee deposited by the clinics/banks for the purpose of registration shall be utilized by the Appropriate Authority of the States/UT in connection with the activities connected with the implementation of the ART Act, 2021. The Instructions regarding utilization of fees dated 21.12.2023 has been issued by DHR to all states/UTs

**62. Is inspection of clinic or a bank mandatory prior to registration?**

Reply: Yes. Registration of clinic or bank will not be granted unless the State Board has inspected the premises of the applicant. (*Section 16(5) of ART Act, 2021*).

**63. Should an opportunity for a hearing be given before rejecting an application for registration?**

Reply: Yes. No application can be rejected unless the applicant has been given an opportunity of being heard in the matter. (*Section 16 (ii) of ART Act,2021*)

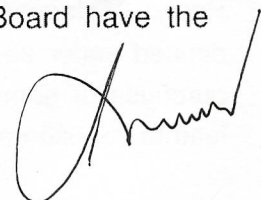
**(K) Inspection & Monitoring**

**64. Who can inspect the premises of a clinic or bank**

Reply: The National Board, the National Registry, the State Board and State Appropriate authority have the power to inspect any premises relating to assisted reproductive technology or call for any document or material

**65. Who has the power to conduct search and seizure of clinic/bank.**

Reply: The National Board, the National Registry or the State Board have the



power to enter and search facility using assisted reproductive technology if there is a reason to believe that an offence under this Act has been or is being committed at any facility using ART.

**66. Can the appropriate authority inspect ART clinics and banks?**

Reply: Yes. The appropriate authority has the power to inspect premises and call for documents to ensure compliance of the Act.

**67. What actions can the appropriate authority take against non-compliant ART clinics?**

Reply: The authority can suspend or cancel registrations, conduct inspections, and take legal action against non-compliant clinics.

**(L) Appeals**

**68. How appeal can be filed?**

Reply: Appeal can be filed by the clinic or bank or the commissioning couple or the woman against an order of the Appropriate Authority, within a period of 30 days from the date of receipt of the communication or order passed by the appropriate authority

(a) The Appellant may file an appeal to the State Government, where the appeal is against the order of the appropriate authority of a State;

(b) The Appellant may file an appeal to the Central Government, where the appeal is against the order of the Appropriate authority of a Union territory.

The format of filing appeal is given under Form 4 (Rule 9 of the ART act) **Section 19 ART Act & Rule 9 of ART Rules**.

**(M) offences & Penalties**

**69. Is it allowed to determine the Sex of the child at stage of the IVF or Surrogacy Treatment?**

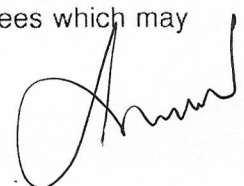
Reply: No. Sex selection is prohibited under the ART Act, 2021 and Surrogacy Act, 2021 and is a punishable offence.

**70. What are the penalties for advertising sex-selective ART services?**

Reply: Offenders face imprisonment for 5 to 10 years and a fine of 10 to 25 lakh rupees.

**71. What constitutes an offence under the Act and what are the penalties imposed for such offences?**

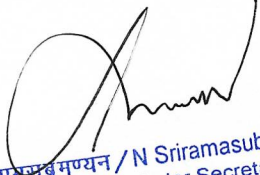
Reply: Offences for the contravention of the provisions of the Act including those defined under section 33(1) such as sex selection, abandonment of child, sale and purchase of gametes and embryos, import of human embryos and gametes etc. can lead to imprisonment for 3 to 8 years and fine not less than 10 lakhs rupees which may



extend to 20 lakhs rupees. [Section 33 (2) of ART Act].

**72. Is ART offenses cognizable and bailable?**

Reply: Yes. All offenses under the Act are cognizable and bailable.



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