### दस्तावेज़ों की सूची

क्र.सं.	विवरण	पृष्ठ सं.

#### MINISTRY OF HEALTH AND FAMILY WELFARE

#### (Department of Health Research)

#### NOTIFICATION

New Delhi, the 21st June, 2022

**G.S.R. 460(E).**—In exercise of the powers conferred by section 50 of the Surrogacy (Regulation) Act, 2021 (47 of 2021), the Central Government hereby makes the following rules, namely: -

- 1. Short title and commencement.- (1) These rules may be called the Surrogacy (Regulation) Rules, 2022.
  - (2) They shall come into force on the date of their publication in the Official Gazette.
- 2. Definitions.- In these rules, unless the context otherwise requires; -
  - (a) 'Act' means the Surrogacy (Regulation) Act, 2021 (47 of 2021);
  - (b) 'form' means a form appended to these rules;
  - (c) 'section' means a section of the Act;
  - (d) words and expressions used herein and not defined but defined in the Act shall have the meanings respectively assigned to them in the Act.
- 3. The requirement, and qualification for persons employed, at a registered surrogacy clinic.- (1) The minimum requirement of staff and their qualification for surrogacy clinic shall be as specified in Schedule I, Part 1.
  - (2) The minimum requirement of equipment for surrogacy clinic shall conform to the requirement as specified in Schedule I, Part 2.
- 4. The manner of application for obtaining a certificate of recommendation by the Board shall be as specified in Form 1.
- 5. Insurance coverage.- (1) The intending woman or couple shall purchase a general health insurance coverage in favour of surrogate mother for a period of thirty six months from an insurance company or an agent recognized by the Insurance Regulatory and Development Authority established under the provisions of the Insurance Regulatory and Development Authority Act, (41 of 1999) for an amount which is sufficient enough to cover all expenses for all complications arising out of pregnancy and also covering post- partum delivery complications.

- (2) The intending couple/woman shall sign an affidavit to be sworn before a Metropolitan Magistrate or a Judicial Magistrate of the first-class giving guarantee as per clause (q) of sub section (1) of section 2 of the Surrogacy (Regulation) Act, (47 of 2021).
- 6. Number of attempts of surrogacy procedure.- The number of attempts of any surrogacy procedure on the surrogate mother shall not be more than three times.
- 7. Consent of a surrogate mother.- The consent of a surrogate mother shall be as specified in Form 2.
- 8. Number of embryos to be implanted in the uterus of the surrogate mother.- The gynaecologist shall transfer one embryo in the uterus of a surrogate mother during a treatment cycle:
  - Provided that only in special circumstances up to three embryos may be transferred.
- 9. Conditions under which the surrogate mother may be allowed for abortion.- The surrogate mother may be allowed for abortion during the process of surrogacy in accordance with the Medical Termination of Pregnancy Act, 1971 (34 of 1971).
- 10. Form and manner for registration and fee for a surrogacy clinic.—(1) An application for registration for a surrogacy clinic shall be made by the surrogacy clinic which is carrying out procedures related to the Surrogacy, as provided in the Act to the appropriate authority in Form 3.
  - (2) Every application for registration shall be accompanied by an application fee of rupees two lakhs for surrogacy clinic and the application fee once paid shall not be refunded:

Provided that, if an application for registration of any surrogacy clinic is 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:

Provided further that such establishment in the government run institutes need not pay for application.

- 11. Period, manner and form for certificate of registration.- (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 Form 4 to the applicant.
  - (2) A copy of the certificate of registration shall be displayed by the registered surrogacy clinic at a conspicuous place at its place of business.
- 12. Appeal.- (1) The surrogacy clinic, or the intending woman, or couple may, within a period of thirty days from the date of receipt of the communication relating to order of rejection of application, suspension or cancellation of registration by the appropriate authority under section 13 and communication relating to rejection of the certificates under section 14, prefer an appeal against such order.
  - (2) The form of appeal shall be as specified in Form 5.
- 13. Manner in which the seizure of documents, records, objects, etc., shall be made and seizure list shall be prepared and delivered.- (1) Every surrogacy clinic shall allow the National Board or National Registry or State Board or Appropriate Authority or to any other person authorised in this behalf to inspect the place, equipment and records.
  - (2) An inspection of an already registered clinic may be done without any notice, during the working hours of the clinic.
  - (3) The authorities referred to in subsection (1) shall ensure that the entry and search procedure do not place at risk the gametes or embryos stored in the facility.
- 14. Medical indications necessitating gestational surrogacy.- A woman may opt for surrogacy if; -
  - (a) she has no uterus or missing uterus or abnormal uterus (like hypoplastic uterus or intrauterine adhesions or thin endometrium or small uni-cornuate uterus, T-shaped uterus) or if the uterus is surgically removed due to any medical conditions such as gynaecological cancer;
  - (b) intended parent or woman who has repeatedly failed to conceive after multiple In vitro fertilization or Intracytoplasmic sperm injection attempts. (Recurrent implantation failure);

- (c) multiple pregnancy losses resulting from an unexplained medical reason. unexplained graft rejection due to exaggerated immune response;
- (d) any illness that makes it impossible for woman to carry a pregnancy to viability or pregnancy that is life threatening.

[F. No. U.11019/15/2022-HR(Pt.)] GEETA NARAYAN, Jt. Secy.

#### **SCHEDULE 1**

#### Part 1

[See rules 3 (1)]

- (1) Staff of surrogacy clinics.- Surrogacy clinics shall have at least one gynaecologist, one anesthetist, one embryologist and one counselor. The clinic may employ additional staff by the Assisted Reproductive Technology Level 2 clinics; normally Director, Andrologist and shall appoint such staff as may be necessary to assist the clinic into day-to-day work.
- (2) Qualification for doctors and other staff in surrogacy clinics.- The qualification of staff in surrogacy clinics shall be as under:
  - (a) Gyanecologist: The gyanecologist shall be a medical post-graduate in gyanecology and obstetrics and should have record of performing 50 ovum pickup procedures and at least three years of working experience in an ART clinic under supervision of a trained ART specialist (In the case of gynecologists practicing ART or IVF and are working in ART clinics before the commencement of this Act a post graduate degree in gynecology and obstetrics with at least three years experience and record of 50 ovum pickup procedures shall be acceptable); or

A medical post-graduate in gynaecology and obstetrics with super specialist Doctorate of Medicine/Fellowship in reproductive medicine with experience not less than three years of working in an Assisted Reproductive Technology clinic.

- (b) Andrologist shall be a Master of Chirurgiae or Diplomate of National Board in urology with special training in diagnosing and treating male infertility.
- (c) Embryologist: (i) Postgraduate in clinical embryology (graduated with the full-time program with a minimum of four semesters) from a recognised university or institute with additional three years of human ART laboratory experience in handling human gametes and embryos;
  - (ii) Ph.D. holder (full-time, Ph.D. project should be related to Clinical Embryology/assisted reproductive technology/fertility) from a recognised university or institute or with an additional one year of human ART laboratory experience in handling human gametes and embryos;
  - (iii) Medical graduate (MBBS) or Veterinary graduate (BVSc) with a postgraduate degree in Clinical Embryology (full-time program) from a recognised university or institute with additional two years of ART laboratory experience in handling human gametes and embryos;
  - (iv) Postgraduate in life sciences/Biotechnology with at least one year of on-site, full-time clinical embryology certified training in addition to four years experience in handling human gametes and embryos in a registered ART level 2 clinics.

As a one-time measure all embryologists working in Assisted Reproductive Technology or In vitro fertilization clinics before the commencement of the Act, with the following below mentioned qualifications and experience may be allowed to continue as embryologists. However, after the commencement of this Act, all clinics will hire Embryologists only with any of the above-mentioned four qualifications and experience criteria.

Graduate in Life Sciences /biotechnology/ reproductive biology/ veterinary science with at least five years experience of working in a registered Assisted Reproductive Technology / In vitro fertilization clinic, who have performed at least 500 IVF lab procedures (including Intracytoplasmic sperm injection I and at least 100 cycles of cryopreservation of embryos).

- (d) Counselor: A person who is a graduate in psychology or clinical psychology or nursing or life sciences from a recognised university or institute.
- (e) Anesthetist: Anesthetist shall be a medical postgraduate in Anesthesia from a recognised university or institute.
- (f) Director: The director should have a post-graduate degree in medical /life sciences/Management Sciences from a recognised university or institute.

#### **SCHEDULE 1**

#### Part 2

#### [see rule 3(2)]

- 1. Equipments: Microscope:
  - (a) Incubator (minimum 02 in number);
  - (b) Laminar Airflow;
  - (c) Sperm counting Chambers;
  - (d) Centrifuge;
  - (e) Refrigerator;
  - (f) Equipment for cryopreservation;
  - (g) Ovum aspiration pump;
  - (h) Ultrasonography machine with transvaginal probe and needle guard;
  - (i) Test tube warmer;
  - (j) Anesthesia resuscitation trolley.

#### FORM 1

#### [See rule 4]

Application Form for Couple of Indian Origin/Intending woman for availing Surrogacy addressed to Board

I/ We (Details as given below) request for a certificate of recommendation for availing Surrogacy Services

- 1. Basic Information
- 1.1 Details of Intended Father:
  - 1. Name:
  - 2. Surname:
  - 3. Date of Birth:
  - 4. Blood Group:
  - 5. Age in years:
  - 6. Sex: Male/ Female

7.

Nationality:

								Sionatuu	e of the	- Intend	ed Mothe
Place:											
Date: .						Signat	ture of 1	the Inten	ided fat	her	
		e that tl	he above sta	atements are t	rue to t	the best of	my kno	wledge a	nd belie	ef.	
Declar	ation										
1.3	Briefly	descri	be the reas	on for availi	ng sur	rogacy					
	14.	•	ort Number								
	13.		•	umber or Equ	ıivalen	t					
	12.	Email									
	11.	_		No. (Details o	of num	ber in India	a and the	e country	of resid	dence)	
		(ii)	Permaner								
		(i)	Present:								
			idence)	o C details 0	1001	-55 111 111010		LACIO UNA	one pre		-0
	10.			give details o			a if avai	lable and	the pre	sent fore	ign
	9.	•		arried/ Divor	ced /W	'idow					
	7. 8.		nanty: pation:								
	6. 7.	Sex:	nality:	Male		remale					
	5. 6		n years	Mala		Female					
	4. 5		Group:								
	3.		of Birth:								
	2.	Surna									
	1.	Name									
1.2			Intended N	viother:							
1.0	14.	•	ort Number								
	13.		•	umber or Equ	ıivalen	t					
	12.	Email									
	11.	•		No. (Details o	of num	ber in India	a and the	e country	of resid	dence)	
		(ii)	Permaner		_					_	
		(i)	Present:								
			idence)	51,0 0000110		-ss in man		inoro una	ine pre	23111 1010	-0**
	9. 10.			give details o			a if avai	lable and	the nre	sent fore	ion
	9.	•		arried/ Divor	cod /W	/idow					
	8.	Occur	oation:								

#### Self attested Documents required for applying

6.

would-be genetic parents).

- 1. Proof of marriage / Marriage Certificate (If applicable)
- 2. Proof of age/Birth certificate/10<sup>th</sup> certificate/ or any equivalent.

( Note: Certificate of essentiality is to be obtained from appropriate authority and Certificate of Medical Indication is to be obtained from the District Medical Board)

#### FORM 2

#### [See rule 7]

#### Consent of the Surrogate Mother and

		Agreement for Surrogacy	
I,		(the woman), aged Years (address) (Aadhar Number), having (Number of children)	
couple/	inten	n (age in years) of my own have agreed to act as a surrogate mother for Intending ding woman Name Husband Name Wife/Intending woman Age Husband Age Wife/Intending woman had a full discussion with Dr of the Surrogacy	
clinic c	on	in regard to the matter of my acting as a surrogate mother for the n of the above 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.	
2.	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 the father becoming seropositive for Human immunodeficiency (HIV) during the window period.		
3.		I consent to the above procedures and the administration of such drugs that may be necessary sist in preparing my uterus for embryo transfer, and for support in the luteal phase.	
4.		I understand and accept that there is no certainty that a pregnancy may result from these edures.	
5.		I understand and accept that the medical and scientific staff may give no assurance that any nancy will result in the delivery of a normal and living child or children.	

7. That I have worked out medical and other 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 shall keep confidential. A General health insurance coverage in favor of the surrogate mother from an insurance company or an agent recognized by the Insurance Regulatory and Development Authority established under the Insurance Regulatory and Development Authority Act, 1999 (41 of 1999) has been purchased by the intending couple/woman.

That I am unrelated or related (relation) \_\_\_\_\_\_\_ to the couple (the

Dated:

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/ woman, as soon as I am permitted to do so by the
	hospital or clinic or nursing home where the child or 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 or 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 or children that I deliver and that the child or children would have all the inheritance rights of a child or children of the biological parent(s) as per the prevailing law.
12.	That I shall 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 Medical Termination of Pregnancy Act, 1971 (34 of 1971).
14.	That I certify that I have not born 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 shall 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 shall not use drugs intravenously, or undergo blood transfusion excepting of blood obtained through a certified blood bank on 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 the party seeking my help as the surrogate mother, I shall deliver the child/children to or in this order; I shall be provided, before the embryo transfer into me, a written agreement of the above persons that they shall be legally bound to accept the child or children in the case of the above-mentioned eventuality. (If applicable)
(Strike	off if not applicable.)
Endor	sement by the Surrogacy Clinic
I/we h	have personally explained to and the details and ations of his / her / their signing this consent / approval form, and made sure to the extent humanly e that he / she / they understand these details and implications.
Signed	<b>:</b>
(Surro	gate Mother)
Signat	ure of Intending couple/Woman
Name,	address and signature
of the	Witness from the Surrogacy clinic
Name	and signature of the Doctor
Name	and address of the Surrogacy Clinic

## FORM 3

## [See rule 10]

### APPLICATION FORM

### REGISTRATION OF A SURROGACY CLINIC

vame	of the Surrogacy clir	nic:						
Addre	ess of the Surrogacy c	linic:						
State:	-	_ City:	P	in Code:				
Telepl	hone No. (with STD	Code) (Surrogacy	clinic only):					
Mobil	e No. of Surrogacy c	linic						
E-mai	l (Surrogacy clinic):							
Websi	ite, if any							
1.	Status of your Surr	ogacy clinic:						
	1. Government	2. Private	e					
	Any other, please s	specify						
2.	Date of establishme	ent of your Surrog	acy clinic:					
3.	Whether your Sur details) Yes / No	rogacy clinic is	registered under follow	ving Acts/A	Authorities (Please providence)			
	1. The Medical Ter	rmination of Pregr	nancy (MTP) Act, 1971	(44 of 1971	)			
	2. The Pre-Conception and Pre-Natal Diagnostic Techniques (Prohibition of Sex Selection) Ac 1994 (57 of 1994)							
4.	Whether your Surrogacy clinic has Director							
	(1. Yes	2. No)						
	a) Name							
	b) Qualification	b) Qualification						
	c) Registration No.	c) Registration No. if applicable						
5.	Details of staff							
	Post	Name	Qualification	_	stration No. if icable			
	Gynaecologist							
	Anesthetist							
	Clinical Embryologist							
	Andrologist							
	Counsellor							

7.	Indicat	e which of the following procedures are being carried out at your Surrogacy clinic
	1. Yes	2. No
	(a)	Intra-uterine Insemination using Husband Semen (IUI-H)
	(b)	Intra-uterine Insemination using Donor Semen (IUI-D)
	(c)	In vitro Fertilization-Embryo Transfer (IVF-ET)
	(d)	Intra-cytoplasmic Sperm Injection (ICSI)
	(e)	Processing of semen
	(f)	Storage of gametes (sperm and oocyte) and or embryos of patient
	(g)	Pre-implantation Genetic Testing
	(h)	Any other procedure, please specify
8.	Any ac	lditional Information
	·	DECLARATION
herew		eby declare that the entries in this form and the additional particulars (if any), furnished ue to the best of my knowledge and belief.
Date:		
		FORM 4
		[See rule 11]
		CERTIFICATE OF REGISTRATION
		Surrogacy Clinic
		(To be issued in duplicate)
		Certificate No.:
1.	(47 hereb	rcise of the powers conferred under section 12 (1) of the Surrogacy (Regulation) Act, 2021 of 2021), the Appropriate Authority
	(a)	Name and address of the Surrogacy clinic:
	(b)	Type of institution (Government / Private)
2.	contr	registration is granted subject to the aforesaid Act and Rules there under and any avention thereof shall result in suspension or cancellation of this certificate of registration e the expiry of the said period of three years.
3.	Regist	ration No. allotted
4.		newed Certificate of Registration only: Period of validity of earlier Certificate of Registration
		Signature, Name and Designation of
		the Appropriate Authority
	• • • • • • • • • • • • • • • • • • • •	
Place:		
		SEAL

Display one copy of this certificate at a conspicuous place at the place of business

<sup>\*</sup>Strike out whichever is not applicable or necessary

## FORM 5

## [See rule 12]

	Appeal No./20Made againstto the State Government /Central Government
In the	matter of:
	Name and Address of Appellant
	Versus
	Name and Address of the Authority Whose Order is Challenged Respondent
Most r	respectfully showeth:
	above-mentioned appellant appeals against the order passed by the concerned priate Authority at(Name of place and address) against the appellant in
(detail	s of the case if any)
datad	
	ts forth the following grounds of objection of the order appealed: -
1.	Particulars of the order including number of orders, if any, against which the appeal is Preferred.
2.	Brief facts of the case.
3.	Findings of the Appropriate Authority challenged.
<b>4.</b>	Grounds of appeal.
<b>5.</b>	Copy of the order enclosed along with all the documents relied upon by the Appellant.
<b>6.</b>	
	Any other information/documents in support of appeal
Prayer	
	he appellant, therefore prays for the reasons stated above the order under the appeal be set aside and ed and order deemed just and proper may kindly be passed in favor of the appellant.
	Signature of the Appellant
Place:	
Date:	
Verific	cation
	best of my knowledge and belief and no part is false and nothing material has been concealed therein.

**Signature of the Appellant** 

### List of Documents

S. No.	Particulars	Page No.

"एंड्रोलॉजिस्ट यूरोलॉजी में एमसीएच/डीएनबी या एमएस जनरल सर्जरी या प्रजनन चिकित्सा में एफएनबी/एमसीएच/डीएम के साथ न्यूनतम 2 वर्ष का अनुभव और न्यूनतम 15 सर्जिकल शुक्राणु पुनर्प्राप्ति (अर्थात् पीईएसए /टीईएसए/टीईएसई/एमईएसए/माइक्रोटेसी प्रक्रियाएं) का व्यावहारिक अनुभवी होगा।"

[फा. सं. यू. 11019/15/2022 एचआर] अन् नागर, संयुक्त सचिव

टिप्पणः सरोगेसी (विनियमन) नियम, 2022 को भारत के राजपत्र, असाधारण, भाग II, खंड 3, उपखंड (i) में दिनांक 21 जून 2022 की अधिसूचना संख्या सा.का.िन. 460 (अ) द्वारा प्रकाशित किया गया था और बाद में दिनांक 10 अक्टूबर 2022 की अधिसूचना संख्या सा.का.िन. 772 (अ), दिनांक 14 मार्च 2023 की अधिसूचना संख्या सा.का.िन. 179 (अ) और दिनांक 08 जून 2023 की अधिसूचना संख्या सा.का.िन. 415 (अ) द्वारा संशोधित किया गया था।

## MINISTRY OF HEALTH AND FAMILY WELFARE

# (Department of Health Research)

#### **NOTIFICATION**

New Delhi, the 11th July, 2023

- **G.S.R. 494(E).**—In exercise of the powers conferred by section 50 of the Surrogacy (Regulation) Act, 2021 (47 of 2021), the Central Government hereby makes the following rules, further to amend the Surrogacy (Regulation) Rules, 2022, namely:-
  - 1. (1) These rules may be called the Surrogacy (Regulation) Amendment Rules, 2023.
  - (2) They shall come into force on the date of their publication in Official Gazette.
- 2. In the Surrogacy (Regulation) Rules, 2022, sub-section (b) of Para 2 in Part 1 of Schedule 1 shall be substituted as under:-

"The Andrologist shall be MCh/DNB in urology or MS General Surgery or FNB/MCh/DM in reproductive medicine with minimum 2 years experience and having hands-on experience of minimum 15 surgical sperm retrieval (namely PESA / TESA / MESA / MICROTESE procedures)."

[F. No. U.11019/15/2022-HR]
ANU NAGAR, Jt. Secy.

**Note**: The Surrogacy (Regulation) Rules, 2022 were published in the Gazette of India, Extraordinary, Part II, Section 3, sub-section (i) vide G.S.R. 460 (E) dated 21st June, 2022, and subsequently amended vide notification number vide G.S.R. 772 (E) dated 10th October, 2022, G.S.R. 179 (E) dated 14th March, 2023 and G.S.R. 415(E) dated 8th June, 2023.