U.11019/24/2024-HR

भारत सरकार/Government of India

स्वास्थ्य और परिवार कल्याण मंत्रालय/ Ministry of Health & Family Welfare स्वास्थ्यअन्संधानविभाग/ Department of Health Research

(समन्वयअन्भाग/ Coordination Section)

IRCS Building, Red Cross Road, New Delhi- 110001

Dated: 23 December, 2024

To,

Principal Secretary (Health)/Secretary (Health)

[All States/UTs]

Subject: Shifting/mass transfer of the cryopreserved embryos/gametes zygotes/gonadal tissues inventory from one clinic/bank to another clinic/bank on account of closure. Instructions thereof-reg.

Madam/Sir,

I am directed to draw attention to the above noted subject and to say that the procedure for shifting/mass transfer of the cryopreserved embryos/gametes/zygotes /gonadal tissues inventory from one centre to another centre on account of closure shall be as enclosed.

2. This issues with the approval of competent authority.

Yours faithfully,

(N Srirama subramanian) Under Secretary to the Government of India

Tel: 011-23736085

एन श्रीरामसुब्रमण्यन/N Sriramasubramanian अवर सचिव / Under Secretary स्वास्थ्य अनुसंघान विभाग / Deptt. of Health Research स्वास्थ्य एवं परिवार कल्याण मंत्रालय Ministry of Health and Family Welfare भारत सरकार/Govt. of India नई दिल्ली/New Delhi

Copy to: All Nodal Officers: ART /Surrogacy (States/UTs)

<u>Instructions to States/UTs regarding Mass transfer/shifting of embryos/gametes/gonadal</u> tissues from one clinic/bank to another on account of closure of the center.

- (A) Pre-conditions for mass transfer of embryos / gametes from one clinic/bank to another on account of Closure of Clinic/Bank
 - (i) All the cryopreserved embryos/gametes/ gonadal tissue must be duly labelled.
 - (ii) There should be no mixing of the samples.
 - (iii) The receiving clinic/bank must be registered under the ART Act, 2021 and Surrogacy Act, 2021.
 - (iv) Complete records clearly specifying details of the patient in respect of each cryopreserved embryos/ gametes must be taken on record from the clinic/bank.
 - (v) Consent for transfer of the patient to whom the embryos/gametes belong must be taken with documented proof and in case the patients are not responding the documentary proof of the communications by the clinics/bank must be taken on record.
 - (vi) There should be no sale and purchase of the cryopreserved embryos/gametes/gonadal tissues/zygotes.
 - (vii) The mass transfer of the gamete or embryos inventory should not amount to any financial/monetary gain to the clinics/banks.
 - (viii) There should be no damage or risk to cryopreserved embryos/gametes/gonadal tissues etc.
 - (ix) Donor gametes are to be used as per the provisions of ART Act 2021. The Bank shutting down need to pass earlier usage information of the Semen Sample and oocyte donor to the receiving bank.
 - (x) All the unused gametes/embryos are to be used for same commissioning couple / single woman as per the provisions of ART Act 2021.
 - (xi) There should be total observance of provisions of ART Act, 2021 and Surrogacy Act, 2021, Rules and Regulations made thereunder.

Application form for mass transfer/shifting of embryos/gametes/gonadal tissues from one clinic/bank to another on account of closure of the center.

Details of the transferring clinic/bank:

Name of transferring clinic/bank:

1.

(a)

(c)

Contact Number:

(b)	Registration Number of the clinic/bank:
(c)	Address:
(d)	Contact Number:
(e)	Email Address:
(f)	If not registered,
	(i) please specify the reasons:
	(ii) Application Number of clinic/bank (used for applying for registration on the National Registry Portal):
2. or W	Details of the Proprietor/Managing or designated Partner/Executive or Managing hole time Director of the transferring clinic/bank:
(a)	Name:
(b)	Designation:
(c) ·	Address:
(d)	Contact Number:
(e)	Email Address:
3.	Details of the receiving clinic/bank:
(a)	Name of Receiving Clinic/bank:
(b)	Address:
(c)	Contact Number:
(d)	Email Address:
(e)	Registration Number of the Clinic/bank:
4. or W	Details of the Proprietor/Managing or designated Partner/Executive or Managing hole time Director of the receiving clinic/bank:
(a)	Name:
(b)	Designation:
(b)	Address:

(B) Checklist of requisite documents and information to be furnished by clinics/ banks:

- (a) Form 1- Application form (enclosed as Annexure I).
- (b) Form 2- Notarised affidavit from the transferring clinic / bank holding embryos/gametes inventory (Annexure II).
- (c) Form 3- Notarised affidavit from the receiving Clinic / bank willing to receive the embryos/gametes inventory (Annexure III)
- (d) Form 4- Records to be maintained and furnished by clinic as per prescribed format (Annexure IV)
- (e) Form 5- Records to be maintained and furnished by bank as per prescribed format (Annexure V)
- (f) Form 6- Consent form of couple/ individual on a notarized affidavit, if they are contactable (Annexure VI)
- (g) supporting documents as under:
 - (i) Self attested ID proofs of couple (husband & wife) / individual.
 - (ii) Documentary evidence (Phone call, WhatsApp, Email, Postal communication etc.) of commissioning couple / singles who could not be contacted or not ready to give consent. (Form 7-Annexure VII)
 - (iii) copy of registration certificates of the receiving and transferring clinic/bank.

(C) Procedure to be followed:

- (i) The applicant has to submit information/documents (as applicable in their case) as per checklist in para (B) above to Department of Health Research (DHR) by email on support-artsurrogacy.gov.in.
- (ii) Screening of the application for deficiencies (if any) by DHR.
- (iii) Communication of the discrepancies (if any) to the applicants through email.
- (iv) Seeking recommendation of Experts Members of the National Board on the applications received by DHR which are complete in all respects.
- (v) Examination of the applications by the Expert Members of the National Board.
- (vi) Final Decision on the application by the National Board.
- (vii) After the approval of Chairperson of National Board, permission letters for mass transfer will be issued by DHR.
- (viii) Acknowledgement from the receiving clinic / bank post receiving the gamete(s)/ embryos/gonadal tissues cryo- inventory etc.

(d)	Email Address:	
5.	Transfer from:	(name of the city
	ate) to	
6.	Reason/purpose of shifting/transfer:	

7. Details of embryo/gametes:

S.No.		Total Number	Quantity No. of containers	
1.	Embryos	(i) Created using patient's own gamete (Self sperms + Self eggs)		
		(ii) Created using patient's own/self-gamete+ Donor gametes (Self sperm + Donor Eggs or Self eggs + Donor Sperm)		
		(iii) Created using both Donor gametes (donor eggs+ donor Sperm)		r 182776-71180928
2.	Gametes			
(i)	Semen Samples	(i) Number of Donor Semen samples	14111111	a ol 2 monace
		(ii) Number of Patient's own/self- Semen samples		
(ii)	Oocytes	(i) Number of Donor oocytes samples		
		(ii) Number of Patients own/Self oocytes samples		
3.	Any other sample such as gonadal tissues etc. (if, any)			

Note: Strike off what is not applicable.

8. Date of applying:

9. Declaration

I hereby declare that all the entries in the above application and the additional particulars, if any, furnished herewith are true to the best of my knowledge and belief. The above transfer of gamete/embryos inventory shall be done in accordance with provisions of the ART (Regulation) Act, 2021 and Surrogacy (Regulation) Act, 2021 and Rules made thereunder.

10. List of supporting documents:

- (i) Copy of Registration Certificates of both the transferring and receiving clinic/bank.
- (ii) Id proof of the Proprietor/Managing or designated Partner/Executive or Managing or Whole time Director of the transferring and receiving clinic/bank.
- (iii) Notarized affidavit on non-judicial stamp paper from both transferring and receiving clinic/bank as specified in (Annexure-II & Annexure III).

- (iv) Detailed records to be furnished by clinics/banks as per prescribed formats (Annexure-IV & Annexure-V)
- (v) Copies of consent forms of patients (if they are contactable) (Annexure VI) along with self-attested ID proofs of the patients
- (vi) Documentary evidence (Phone call, WhatsApp, Email, Postal communication etc.) for patients who could not be contacted or not ready to give consent. (Annexure VII)

Name of the Proprietor/Managing or designated Partne time:	er/Executive or Managing or Whole
Director of the transferring clinic/bank:	
Signature & Seal/stamp:	
Date:	
Place:	

AFFIDAVIT FROM TRANSFERRING CLINIC / BANK

1,		S/o	
aged	years,	functioning	as
	, in		
having	Registered	Office	at
		al address), do hereby solemn	
and state as under:-	•		,
That	(Name &	Address of transferring clini	c/bank) bearing
registration number/app	plication		is willing to
transfer the		. (Total Numbers) embryo/gan	iete inventory to
			(name of
the receiving clinic/ba	nk and address) on acco	ount of closure of the clin	ic/bank due to
		(reas	
I further State that:		(Teas	on closure).

- The cryopreserved samples have not been subjected to any procedure resulting into sex selection and separation of X or Y fractions.
- There is no mixing of the samples and each sample has been duly labelled for identification purposes.
- There will no damage or risk to cryopreserved embryos/gametes/gonadal tissues etc.
- There is no sale or purchase/trade involved in the current transfer.

I understand that selling human embryos or gametes, running an agency, a racket or an organization for selling, purchasing or trading in human embryos or gametes shall be a punishable offence.

Details of the cryopreserved samples:

- 1. Total Number of Embryos (in no.& containers):
- 2. Total Numbers of semen sample vials (in vials):
- 3. Total number of oocytes (in no.& containers):
- 4. Other cryopreserved tissues & sample etc. (if, any):

Declaration

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

Name & Signature of the Proprietor/Managing or designated Partner/Executive or Managing or Whole time Director of the clinic/bank:

Depone
(Seal/Stamp
Date: Place:
Verification
Verified at on this day of, 2024 that the contents of the above affidavit are true and correct to the best of my knowledge and belief and nothing material has been concealed here from.
Deponen
(Seal/Stamp

*Note: The Affidavits shall be executed on Non-Judicial Stamp paper duly sworn before Metropolitan Magistrate or a Judicial Magistrate of First Class or an Executive Magistrate or a Notary Public.

AFFIDAVIT FROM THE RECEIVING CLINIC / BANK.

I,		, S/o	,
aged	years, functioning as		,
in			
	ce at		
	o hereby solemnly swear, affi		
That			
	(Name & Address of	receiving clinic/bank)	bearing registration
number	is willing to	receive the	(Total
Numbers)	embryo/gamete	inventory	from
			(name of
the transferring clinic/t	oank and address).		

I further state that:

- The cryopreserved samples will be used for the purpose of treatment of respective patients only/ or for future storage or research purposes in India in accordance with the ART (Regulation) Act, 2021 and Surrogacy (Regulation) Act, 2021.
- The frozen sample will not be subjected to any procedure resulting into sex selection and separation of X or Y fraction.
- There is no sale or purchase/trade involved in the current transfer.

I understand that selling human embryos or gametes, running an agency, a racket or an organization for selling, purchasing or trading in human embryos or gametes shall be a punishable offence.

I further acknowledge that [Name of transferring clinic/bank] has no further responsibility for the storage or handling of these embryos/gametes following the transfer to our clinic/bank. The Storage and handling of the cryopreserved samples shall be in accordance with the provisions of ART (Regulation) Act, 2021 and Surrogacy (Regulation) Act, 2021.

Details of the cryopreserved samples:

- 1. Total Number of Embryos (in no.& containers):
- 2. Total Numbers of semen sample vials (in vials):
- 3. Total number of oocytes ((in no.& containers):
- 4. Other cryopreserved tissues & sample etc. (if, any):

And Market State of the State o

Declaration

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

Name & Signature of the Proprietor/Managing or designated Partner/Executive or Managing or Whole time Director of the clinic/bank:

	Deponent
	(Seal/Stamp)
Date:	enting which
Place:	
Verific	cation
Verified at on this day of affidavit are true and correct to the best of my knd concealed here from.	f, 2024 that the contents of the above owledge and belief and nothing material has been
*Note: The Affidavits shall be executed on Non-Jud Magistrate or a Judicial Magistrate of First Class or	
	Deponent
	(Seal/Stamp)

FORMATS FOR MASS TRANSFER OF GAMETES/EMBRYOS FROM ONE CLINIC/BANK TO ANOTHER ON ACCOUNT OF CLOSURE OF CLINICS/BANK

(i) FORMAT OF RECORDS TO BE MAINTAINED AND FURNISHED BY CLINIC:

Sno	Reg No (UHID)	patient (i) Single Man (ii) Single Woman (divorce d/widow/unmarr ied) (iii) Married Couple	(Self or Donor) or (ii) Egg/oocytes	Status of the patient	Patient	of the patient	Id of patient	Single woman (divorced	and (in case of married	Total number of Embryos or / Semen Vial / or Oocyte)	Freezing embryos/	Viral Markers report (Yes/No)	Consent attached (yes/No)



Form 5

(ii) FORMAT OF RECORDS TO BE MAINTAINED AND FURNISHED BY BANK:

Sno	/ Patient ID	number	Individual	Status of	Type of sample (i) semen sample	e Donor/	the Donor/	f the	(if	Donor	(s) of the	Total number of Semen Vial	cryo Straws/	Date of collection	Test reports
		,		Patient/ or Donor	Or (ii) Egg/oocytes)	or Patient		Patient	available) of the Donor/ Patient		Donor/ Patient	or / Oocytes (as applicable)	containers		(HIV, HBV, HCV, VDRL etc): (Y/N)
			Donor Or (b) Oocyte dono r												
			*												
															-



Form 6

AFFIDAVIT FOR CONSENT of COUPLE /INDIVIDUAL FOR SHIFTING OF EMBRYOS/GAMETES

(To be submitted by the Couple / Single Individual only)

	e of	the individual/couple), aged years, reside	nt(s)
receiv	ing clir	esidential Address), hereby consent to shift my/our(num (embryos/semen vial/oocytes) to (name & address of c/bank).	the
for		the purpose	of
(i)	Date of	f freezing embryos/sperms/oocytes(DD/MM/	YY)
(ii)	Embr	os created using (if applicable)	
	(a)	self-gametes (sperm of Husband & oocyte of wife)	
	(b)	using one donor gametes (sperm of donor & oocyte of wife or oocyte of donor & sp	erm
		of husband:	
	(c)	using both donor gametes (sperm of donor and oocyte of donor).	
(iii)	(a)	Name & Address of the clinic/bank holding/transferring clinic/bank:	
	(b)	frozen for the purpose of	tion.
		DECLARATION:	
		declare that the entries in this affidavit and the additional particulars, if any, furnished to the best of my knowledge and belief.	shed
Date:			
Place	:		
Paste	duly at	ested Photo of Husband and Wife /Individual (as applicable)	
Name	and Sig	nature of couple (Husband & wife) / Individual (as applicable)	

*Note: The Affidavit shall be executed on Non-Judicial Stamp paper duly sworn before Metropolitan Magistrate or a Judicial Magistrate of First Class or an Executive Magistrate or a Notary Public. In case the applicant is outside India then the Affidavit shall be executed through an authorized Attorney in India. Note: Strike off which is not applicable

Form 7

Format for clinic reg. Documentary Evidence in scenarios where patient is not contactable

	Category of patient (i) Single Man Or (ii) Single Woman (divorced/widow /unmarried) or (iii)Married Couple	Status of the patient	(i) semen sample (Self or Donor) Or (ii) Egg/oocytes (Self or Donor) Or	Name of the Patient (In case of Married couple provide details of both husband and wife)	Mobile no of patient	Age of wife/Single woman (divorced/ widow/ unmarried)/ single man	Total number of Embryos / S emen Vial / O cyte)	Straws/ contain	Date of Freezing embryos/ Gametes	Proof of documentary evidence attached) Phone call, WhatsApp, Email, Postal communicatio n etc.) please specify

