



Informed consent and request to cryopreservation of embryos

No _____ on _____

Mrs.	
Address	ID
Phone	Email

Mr.	
Address	ID
Phone	Email

as patient / patients of Gynera Fertility Clinic, jointly request the cryopreservation of the viable embryos that are not transferred to the uterus, resulted from IVF (in vitro fertilization) procedure performed at the clinic or transferred from another unit, under the conditions agreed and detailed below.

We understand that assisted reproduction techniques with cryopreserved embryos are optional treatments and are not always successful. We have considered available options before choosing cryopreservation.

We have been informed about cryopreservation and storage of embryos in liquid nitrogen and we understand that:

I. Purpose and procedure

Cryopreservation enables to preserve embryos in a frozen state (-196°C) for future use.

The following steps are involved in the cryopreservation of embryos: patients' evaluation, IVF procedure, selection of embryos suitable for cryopreservation, freezing and storage.

The investigations prior to cryopreservation of embryos are necessary to detect conditions that may affect the outcome and identify the risk for transmitted diseases. These include infectious disease tests for both partners.

Embryos may be frozen at early stages, on Day 2 or 3 of development, or at blastocyst stage, on Day 5 or 6. They are frozen in the clinic by vitrification technique, or transferred under special conditions from another Embryo Bank.

The embryos are rapidly frozen to very low temperatures, below -196 ° C and kept in this state in liquid nitrogen.

The storage requires controlled conditions; monitoring and supply of liquid nitrogen are performed on a permanent basis, by qualified personnel. Embryos may be frozen singly or in pairs in one carrier (straw).

Always at least one carrier is thawed. After thawing, embryos are cultured in special culture medium.

Once an embryo is thawed, it might not be suitable for re-freezing.

The embryo transfer to the uterus after thawing is done in a natural cycle or in an artificial cycle (controlled by medication). The hormonal balance is necessary for the uterus to allow the implantation of embryo. The natural cycle is monitored to detect ovulation and the most favourable day for implantation. In an artificial cycle (hormone replacement), estrogen and progesterone are administered in doses similar to those produced in natural cycles, to prepare the uterus for implantation. Medication to control the spontaneous hormonal cycle may be associated in ovulatory women. Treatment is monitored by ultrasound and hormone tests to determine the embryo transfer date. Depending on the stage of embryos, the transfer may be performed on the thawing day or after further culture. Embryos that do not survive the thawing process are eliminated according to the regulations in force.

II. Success rate

The survival rate after thawing depends on the embryo quality, but also on other factors, not always identifiable.

Most embryos resume their development after thawing. Under current conditions, the success rate of frozen embryo transfers is similar to fresh embryo transfers.

III. The risks of cryopreservation of embryos

Cryopreservation procedure does not guarantee the viability of the embryos after thawing, nor the normal development of embryos or pregnancy.

Although safety measures are taken, there is still a risk of natural calamities during embryo manipulation and storage or other events beyond the control of the storage facility,. The Gynera Clinic has implemented advanced procedures, including: backup equipment, monitoring, electronic witnessing procedures, epidemiological testing, quality control. However, unavoidable accidents cannot be excluded. In the event of unforeseen accidents, the clinic cannot be held liable for the loss of frozen embryos and does not provide financial compensation.

If the Embryo Bank ceases its activity or can no longer continue to store samples, the clinic will make all reasonable efforts to facilitate their utilisation or transfer to another unit, according to patients' decision. If a patient chooses to transfer the cryopreserved samples to another unit, he will have full and sole responsibility for the transport, disposition and subsequent utilisation of frozen embryos. Until now, there is no evidence that cryopreservation process would increase the risk of embryonic abnormalities.

IV. Financial terms

The cost of cryopreservation by vitrification and the storage cost for frozen embryos are detailed in the financial protocol. First year storage is free of charge for embryos cryopreserved at Gynera Clinic.

First 6 months storage is free of charge for embryos transferred from another unit.

After expiration of the free of charge period, the storage may be prolonged by paying the annual storage fee and confirming payment. The maximum storage period is 5 years.

According to current law, patients who choose to cryopreserve embryos should be tested for hepatitis B and C, HIV and lues on the day of procedure, with associated costs. In case of a positive test for infectious agents, the clinic stores the embryos in a quarantine system (separate from other samples) and an additional annual cost is to be paid. Thawing embryos and subsequent embryo transfer involve additional costs.

V. Confirmation. Authorization

We accept investigations and we authorize clinic staff to perform the necessary evaluation, selection, cryopreservation and embryo storage procedures. We declare that we have informed the physician about all facts important for the assessment and for the choice of the optimal treatment. We accept that in case of falsehood of this statement, both the clinic and treating physician will not be liable for the consequences caused thereby.

We confirm that we have made this decision voluntarily without being subjected to physical or mental pressure.

We understand that we will be considered as legal father and legal mother of the child who will be born after the treatment. We also understand that any disposition of cryopreserved embryos requires the written consent of both partners. In case of divorce, death or absence of consensus the clinic acts according to this consent, applicable law or a court order. The clinic reserves the right to deny the transfer to the uterus of cryopreserved embryos if, on the basis of any new scientific evidence or information, it considers that the risks outweigh the benefits.

We agree that during the procedure we will be mutually informed about medical issues or situations that may affect the other partner or the health of the future child conceived by IVF procedure.

We declare that we have been acquainted with the applicable price list of Gynera Clinic, and we undertake to pay the price for technologies and methods we have chosen. The price list is available on the website www.gynera.ro. If we wish to extend the storage, we agree to pay the fee in advance, up to the due date; otherwise, the agreement will cease automatically, and the clinic reserves the right at its sole discretion to make decisions regarding the final disposition of cryopreserved embryos, to continue storage or discard embryos, if the fee obligations are not met.

My/our Signature(s) on this Consent indicate that I / we:

1. Have read and freely agree and consent to all the procedures and to all of the information contained herein;
2. Have been provided with sufficient information and clearly understand the information that I/we have been given about these procedures including their nature, benefits and risks, consequences of acceptance or refusal of procedures, success rate and alternatives as explained to me/us by my/our doctor or other Gynera staff member;
3. Have had the chance to ask questions and have had all of my/our questions answered to my/our satisfaction.

This consent may be revoked by submitting a written request.

We agree hereby to inform the clinic in writing about occurrence of any change important for carrying out the procedure, including medical issues, changes in marital status or contact details (address, phone, email) .

Mrs. _____

Mr. _____

ID _____

ID _____

Unmarried / Married to _____

Unmarried / Married to _____

Signature

Signature

I , _____ hereby confirm that this form has been filled by patients in my presence.

Date _____

Signature