



INFORMATION CONCERNING FREEZING AND PRESERVATION OF OVARIAN TISSUE FOR THE PURPOSE OF PREVENTING INFERTILITY

Dear Madam

This information is intended to explain the procedure of freezing and preservation of ovarian tissue, so that you can consent in full knowledge of the facts.

You have discussed with your doctor the possibility of having ovarian tissue frozen (vitrification) as part of the programme that aims to maintain fertility in patients who are receiving cancer treatment using chemo and/or radiotherapy. These therapies can reduce fertility in women, i.e. they not only destroy malignant cells, but also affect eggs and their precursors in the ovaries.

When chemotherapy and/or radiotherapy will be used, the ovaries can be protected by surgically removing one ovary, which will then be frozen. During this operation (laparoscopy) the ovary will partially or completely be removed and will be frozen before the start of chemotherapy and/or radiotherapy.

The frozen ovarian tissue can be used in two ways after the cancer treatment:

- Either mature eggs may be developed from the frozen, immature ovarian tissue in the fertility laboratory (this process is also referred to as 'in vitro maturation'). These eggs can then be fertilised with the partner's sperm in order to create embryos that will be transferred to the uterus. Unfortunately this in vitro maturation technique has currently not been developed sufficiently to be applicable in clinical practice. However, research on this topic is ongoing and it is not unthinkable that this method might be an established technique in the future.
- Or the frozen ovarian tissue may be thawed and may be prepared to transplant back into the body. This procedure is currently also at an experimental stage, but various centres have issued encouraging reports and the technique may well become available for clinical practice in the near future.

The agreement you will enter into with the Leuven University Fertility Centre (LUFC), concerning the freezing and storage of ovarian tissue, does not compel either party to proceed with treatment.

Before proceeding with the freezing and preservation of ovarian tissue aiming to meet the desire to have a child now or in the future, you should sign an agreement in which you indicate the destination of the frozen ovarian tissue, in keeping with the law of 6 July 2007 on medically assisted reproduction and the use of extra embryos and gametes.

In this agreement, you should indicate the destination of the frozen ovarian tissue:

- When the stated storage period of the ovarian tissue has expired.
- In the event that you will permanently be incapable of making decisions or in the event of your death.

You have a choice between following destinations for the frozen ovarian tissue:

- to relinquish the frozen ovarian tissue for scientific research (in accordance with the law of 11 May 2003 on research on embryos in vitro);
- to destroy the frozen ovarian tissue.

By law, the storage period for frozen ovarian tissue is ten years. This period starts on the day the tissue is frozen for storage.

On explicit request or in special circumstances, the period may be shortened or extended, although this must always be with the agreement of the LUFC. The LUFC may refuse a request to extend the storage period.

Within the agreed period, it is also possible to change the intended destination of the frozen ovarian tissue in the original agreement. This change of the destination will be included in a new agreement signed by all parties.



INFORMATION CONCERNING FREEZING AND PRESERVATION OF OVARIAN TISSUE FOR THE PURPOSE OF PREVENTING INFERTILITY

A request to modify the agreement must be sent by registered letter to Leuvens universitair fertiliteitscentrum, contractenadministratie, UZ Leuven, Herestraat 49, 3000 Leuven.

On the expiry of the period, the LUFC will carry out the instructions given by you in this agreement.

The information relating to relinquishing the frozen ovarian tissue for scientific research can be found in the attached documents:

- [Information on relinquishing frozen ovarian tissue for scientific research](#)

UZ Leuven will not charge patients more than the official non-refundable part of medical expenses, in accordance with the nomenclature of medical supplies, for the laparoscopic removal of the ovary tissue and for the required additional examinations and consultations that are directly related to the treatment for and technique of cryopreservation of ovary tissue.

The procedure of freezing and preservation of ovarian tissue is labour-intensive and expensive for the LUFC. Therefore we are forced to charge a fixed fee during the statutory period of ten years. [The one-off cost for freezing amounts to EUR 519,75 \(excluding VAT\) as at 1 January 2018.](#) This amount will be adjusted 1 January each year in line with the health index (<http://statbel.fgov.be/nl/statistieken/cijfers/economie/consumptieprijzen/gezondheidsindex>) in the preceding December. [The storage charges will be invoiced in two-year instalments. The date of freezing is the start date for the payments. The fee for each new two-year period must be paid in full in advance.](#) If you no longer wish the ovarian tissue to be stored, you should inform the LUFC of this at least two months before the end of the current period, by sending a letter by recorded delivery to Leuven University Fertility Centre, contractenadministratie, UZ Leuven, Herestraat 49, 3000 Leuven. If this recorded delivery does not reach us in time, you will be charged for the costs of storage for the following two-year period. The fixed fee amounts to EUR 160,35 per two year period (excluding VAT) as at 1 January 2018. This amount will be adjusted 1 January each year in line with the health index (<http://statbel.fgov.be/nl/statistieken/cijfers/economie/consumptieprijzen/gezondheidsindex>) in the preceding December.

[All these documents are intended for you. If you agree to this treatment, you should complete and sign the attached 'Agreement concerning freezing and preservation of ovarian tissue for the purpose of preventing infertility' and return it to LUFC, 'contractenadministratie', UZ Leuven, Herestraat 49, 3000 Leuven or to \[contractenLUFC@uzleuven.be\]\(mailto:contractenLUFC@uzleuven.be\).](#)



INFORMATION ON RELINQUISHING FROZEN OVARIAN TISSUE FOR SCIENTIFIC RESEARCH

Dear Madam

This information is intended to explain what scientific research can be carried out with frozen ovarian tissue that you no longer wish to store for yourself, so that you can consent in full knowledge of the facts for the option 'to relinquish frozen ovarian tissue for scientific research' as the destination of your frozen ovarian tissue at the end of the storage period.

This scientific research will be conducted by or in collaboration with the Leuven university fertility centre (LUFC) laboratory.

If this option has been chosen, permission may be withdrawn at any time up to when the scientific research begins. The withdrawal must be communicated by registered letter to the LUFC laboratory, UZ Leuven, Herestraat 49, 3000 Leuven.

If this option is chosen, the LUFC will have the opportunity to conduct scientific research into the development and application of new techniques in assisted reproductive technology. The use of frozen ovarian tissue for such research is indispensable.

The following points are important:


- The confidentiality of names and other personal data is strictly guaranteed.
- Any research protocol for which frozen ovarian tissue may be used has first been approved by the Medical Ethics Committee of UZ Leuven and KU Leuven and/or the Medical Ethics Committee of the Faculty of Medicine (KU Leuven) and by the Federal Commission for medical and scientific research on embryos in vitro.
- The scientific research is in accordance with the law of 11 May 2003 on research on embryo in vitro.
- The scientific research relates to:
 - ◆ the development of new procedures for improving the IVF/ICSI and CRYO programmes.
- Participation in these studies will not provide any financial advantages and will not bring any additional costs.
- You give permission for applications for possible patents for any inventions resulting from the research to which you have explicitly consented and waive any claim for compensation on an informed basis.

If you would like more information about this, please contact the laboratory of the LUFC, Herestraat 49, 3000 Leuven (tel. 016 34 08 12 or email: fertiliteitscentrum@uzleuven.be).



AGREEMENT CONCERNING FREEZING AND PRESERVATION OF OVARIAN TISSUE FOR THE PURPOSE OF PREVENTING INFERTILITY

Between Leuven university fertility centre,
UZ Leuven,
represented by
prof. dr. Karen Peeraer,

 en Ms *
born on / /
resident at
.....

* if this person is a minor, the agreement (see Art. 12 of the Belgian law dated 22 August 2002) is concluded between the LUFc and the parents or guardian with authority over the minor. If you are a minor when this contract is signed, you will be offered a new contract when you reach maturity.

hereinafter 'the LUFc', on the one hand,

hereinafter the patient, on the other hand,

the following has been agreed:

- The patient declares that she has received, read and understood the document entitled 'Information concerning the freezing and preservation of ovarian tissue for the purpose of preventing infertility'. She consents to the freezing and preservation of her ovarian tissue by the LUFc, with a view to fulfil a future wish to have children. She is aware of the implications of the freezing and preservation of the ovarian tissue and understands that the current scientific evidence clearly demonstrates that such preservation does not offer any guarantee with respect to successful pregnancy in the future.
- The LUFc will take due care in the freezing and preservation of the ovarian tissue. The LUFc is not liable for the loss of preserved ovarian tissue in cases of force majeure (such as fire, theft, power cuts or other external causes).
- The patient declares that she has received all the necessary information regarding the circumstances and duration of the storage of her ovarian tissue when the stated period comes to expire. By law, the storage period for ovarian tissue frozen with a view to fulfilling a current or future desire to have children is ten years. This period starts on the day on which the tissue is frozen. On the expiry of this period, the LUFc will carry out the instructions given by the patient in this agreement.
- The patient consents to a fixed charge for the freezing of the ovarian tissue. The one-off cost for freezing amounts to EUR 519,75 (excluding VAT) as at 1 January 2018. This amount will be adjusted 1 January each year in line with the health index (<http://statbel.fgov.be/nl/statistieken/cijfers/economie/consumptieprijzen/gezondheidsindex>) in the preceding December.
- The patient consents to a fixed charge for the preservation of the frozen ovarian tissue. The fixed fee amounts to EUR 160,35 per two year period (excluding VAT) as at 1 January 2018. This amount will be adjusted 1 January each year in line with the health index (<http://statbel.fgov.be/nl/statistieken/cijfers/economie/consumptieprijzen/gezondheidsindex>) in the preceding December. If the patient no longer wishes the ovarian tissue to be stored, she should inform the LUFc of this at least two months before the end of the current period, by sending a letter by recorded delivery to Leuven University Fertility Centre, contractenadministratie, UZ Leuven, Herestraat 49, 3000 Leuven. If this recorded delivery does not reach us in time, the costs of storage for the following two-year period will be charged.



AGREEMENT CONCERNING FREEZING AND PRESERVATION OF OVARIAN TISSUE FOR THE PURPOSE OF PREVENTING INFERTILITY

- On explicit request of the patient or in special circumstances, the period can be shortened or extended, although this must always be with the agreement of the LUFC. It is also possible to make changes to the original agreement as regards the intended destination of the ovarian tissue, unless the storage period for the frozen ovarian tissue has expired in the meantime. A request by the patient to change the period or to modify the agreement must be sent by registered letter to Leuvens universitair fertiliteitscentrum, contractenadministratie, UZ Leuven, Herestraat 49, 3000 Leuven.
 - ♦ The LUFC may refuse a request to extend the storage period. In this case, the instruction indicated by the patient in this agreement will be carried out.
- The patient declares that she has received sufficient explanation about the possible options for the destination of the frozen ovarian tissue.
 - ♦ In the event of 'relinquishing frozen ovarian tissue for scientific research' the patient expressly agrees to relinquish her frozen ovarian tissue to the LUFC for scientific research that has been approved by the Medical Ethics Committee of UZ Leuven and KU Leuven and/or the Medical Ethics Committee of the Faculty of Medicine (KU Leuven) and by the Federal Commission for medical and scientific research on embryos in vitro. This research is in accordance with the law of 11 May 2003 on research on embryos in vitro. The patient declares that she has received, read and understood the 'Information on relinquishing frozen ovarian tissue for scientific research'.
 - ♦ In the event of 'destruction of the frozen ovarian tissue' the LUFC will destroy the frozen ovarian tissue without any intervention other than that necessary for destruction.



Madam's initials



*if a minor

Parents' or Guardian's initials



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- The patient declares that she has taken the following decision relating to the destination of her frozen ovarian tissue. She wishes to:

Destination of frozen ovarian tissue

Indicate your decision under A, B and C:

A. On the expiry of the stated period (tick one box only):

- relinquish this ovarian tissue for scientific research *
- destroy this ovarian tissue


B. In the event that the patient is permanently incapable of making decisions (tick one box only):

- relinquish this ovarian tissue for scientific research *
- destroy this ovarian tissue

C. In the event that the patient passes away (tick one box only):

- relinquish this ovarian tissue for scientific research *
- destroy this ovarian tissue

* If the ovarian tissue will not be suitable for scientific research or an abundant number of ovarian tissue will be available for scientific research, this ovarian tissue may not be used for scientific research purposes and may be discarded.

Drawn up in duplicate in Leuven on /...../....., one copy being intended for the LUFC and the other for the patient.

Name Madam

*if a minor, Parents' or Guardian's name


.....

.....

born on / /

born on / /

prof. dr. Karen Peeraer
Administrator Tissue Bank LUFC

 Read and approved
signature Ms.

 *if a minor
Signature of Parent or Guardian

Please complete and sign this agreement and return it to Leuvens universitair fertiliteitscentrum, 'contractenadministratie', UZ Leuven, Herestraat 49, 3000 Leuven or contractenLUFC@uzleuven.be.