



UZ

LEUVEN

GYNAECOLOGIE EN VERLOSKUNDE
Leuvens universitair fertiliteitscentrum

www.uzleuven.be/lufc › tel. +32 16 343624

INFORMATION REGARDING THE STORAGE AND DESTINATION OF SUPERNUMERARY EMBRYOS

Dear Madam, dear partner,

During an in vitro fertilisation (IVF) cycle or intracytoplasmic sperm injection (ICSI) treatment, the ovaries are stimulated hormonally, so that multiple eggs are available for fertilisation. To minimise the risk of multiple pregnancy, the number of embryos implanted in each cycle is restricted by the government in the context of reimbursement of IVF/ICSI treatment (see annex to the Royal Decree of 25 April 2002 on the establishment and settlement of the Financial Resources Budget). Only a limited number of embryos will therefore be implanted in the uterus, depending on the age and the attempt. Since more embryos may be created than can be transferred in the same cycle, there is a chance of supernumerary embryos.

At the Leuven University Fertility Centre (LUFC), these supernumerary embryos will, in general, be frozen, if the quality is sufficient, so that they can be stored with a view to fulfilling an existing or future desire to have children. They will only be frozen if the serological tests for infectious diseases show that all health conditions are met to be able to freeze them.

If you do not wish these embryos to be frozen, you must inform the LUFC by registered letter to Leuvens universitair fertiliteitscentrum, contractenadministratie, UZ Leuven, Herestraat 49, 3000 Leuven. The Law of 6 July 2007 states that as long as frozen supernumerary embryos remain, these must be used first in a thawing cycle, provided they comply with the required health standards, and that no further eggs should be removed to create more embryos. In addition, both partners must consent to a new implantation before any such medical procedure takes place.

If there is no objection to the freezing of the supernumerary embryos, in accordance with the law of 6 July 2007 on assisted reproductive technology and the use of supernumerary embryos and gametes, the agreement in attachment must be signed and the destination of supernumerary embryos must be indicated.

In this agreement, you should indicate the destination of the supernumerary embryos:

- when the stated storage period of the embryos has expired;
- in the event of separation or divorce, if one of the prospective parents is permanently incapable of making decisions or if the prospective parents have a difference of opinion that cannot be resolved;
- if one of the prospective parents passes away.

You have a choice between following destinations for the supernumerary embryos:

- to relinquish these embryos for scientific research (in accordance with the Law of 11 May 2003 on research on embryos in vitro);
- to relinquish these embryos for use in training laboratory staff at LUFC;
- to destroy these embryos.

By law, the **storage period** for supernumerary embryos frozen with a view to fulfilling a current or future desire to have children is **five years**. This period starts on the day of which the embryos are frozen.

On explicit request of the prospective parents 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 supernumerary embryos in the original agreement. This change of the destination will be included in a new agreement signed by all parties.

A request by the prospective parents to modify the agreement must be sent by registered letter to the Leuven University Fertility Centre, Contract Administration/Contractenadministratie, UZ Leuven, Herestraat 49, 3000 Leuven, Belgium.



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

If after signing the agreement the prospective parents are unable to agree on the destination of supernumerary embryos or whether the storage period should be extended, the LUFC will take account of the content of the last agreement signed by both partners.

Use of supernumerary frozen embryos:

- If you choose the option 'relinquish supernumerary embryos for scientific research', you will find more information on relinquishing supernumerary embryos for scientific research in the accompanying document:
 - o [Information on relinquishing frozen supernumerary embryos for scientific research](#)
- If you choose the option 'to relinquish supernumerary embryos for training laboratory staff', this means that the embryos can be used to teach certain techniques to laboratory staff. The majority of techniques such as IVF, ICSI, embryo biopsy, freezing and thawing of embryos have become routine procedures. In order to be able to guarantee the quality of these procedures, it is important that we train the laboratory staff to carry out the technological procedures to the highest possible standard and to learn to constantly improve the existing procedures.
- If you choose the option 'to destroy supernumerary embryos', this means that the remaining embryos will be destroyed without any interventions other than those which are needed for the destruction.

In accordance with the law of 6 July 2007, post mortem (after death) implantation of frozen supernumerary embryos is permitted. Post mortem implantation may take place no sooner than six months and no later than two years after the death of the prospective parent. However, it is not possible to perform post mortem implantation at the LUFC. If this option is chosen in the agreement, frozen supernumerary embryos can therefore be transferred to a recognised centre for reproductive medicine (Type B) designated by the couple. This centre will be responsible for further storage of the embryos under the agreed conditions. The prospective parent is responsible for the transfer of the embryos.

If you would like more information, please contact the laboratory at LUFC, Herestraat 49, 3000 Leuven, Belgium (tel. +32 16 340812 or email: fertiliteitscentrum@uzleuven.be).

All these documents are intended for you. If you agree to this treatment, you should complete and sign the attached 'Agreement on storing supernumerary embryos' and return it to LUFC, 'contractenadministratie', UZ Leuven, Herestraat 49, 3000 Leuven or to contractenLUFC@uzleuven.be.



INFORMATION ON RELINQUISHING FROZEN SUPERNUMERARY EMBRYOS FOR SCIENTIFIC RESEARCH

Dear Madam, dear partner,

This information is intended to explain what scientific research can be carried out with frozen supernumerary embryos 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 supernumerary embryos for scientific research' as the destination of your frozen embryos 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. Your permission can be validly withdrawn at the request of either one of you. The withdrawal must be communicated by registered letter to the LUFC laboratory, UZ Leuven, Herestraat 49, 3000 Leuven.

If this option is chosen, the embryos will be used for research within the limits set by the Law of 11 May 2003 on in vitro embryo research.

This means that the research: (1) has a therapeutic purpose or contributes to increasing knowledge regarding fertility, infertility, organ or tissue transplants, disease prevention or treatment; (2) is based on the most recent scientific findings and meets the required standards for appropriate scientific research methodology; (3) is carried out in or under the supervision of an approved laboratory that is affiliated to a university care programme for reproductive medicine or human genetics and in appropriate technical and material circumstances; (4) is carried out under the supervision of qualified persons; (5) is carried out on embryos during the first 14 days of the development phase, not including the period of freezing; (6) there is no other research method which is equally effective.



INFORMATION ON RELINQUISHING FROZEN SUPERNUMERARY EMBRYOS FOR SCIENTIFIC RESEARCH

The following points are important:

- The scientific research may cover the following fields:

1. In vitro fertilisation and freezing techniques

This research aims to improve existing techniques in the fertility clinic, and to develop and validate new procedures. The focus of the study is on laboratory techniques for fertilising eggs outside the body (in vitro fertilisation or IVF), on the conditions which foster good growth of embryos outside the body and on the best way to freeze and store embryos.

2. Embryonic development and implantation of the embryo in the uterus

Research on embryonic development and in vitro implantation is aimed at increasing our understanding of why embryos fail to grow or fail to implant. Embryonic development begins when the egg is fertilised by a sperm cell and subsequently goes through the different phases of development into a multi-cell embryo, a morula and a blastocyst. This research will shed light on the function of the genes and proteins which play a crucial role in early embryonic development. In vitro models can be used for research on uterine wall implantation. This research may lead to improved diagnosis and treatment of couples with fertility problems.

3. (Epi)genetic status of the embryo

This research focuses on techniques to examine the DNA of embryos before they are implanted in the womb. The best-known application is pre-implantation genetic testing (PGT), in which a small number of cells are removed from the embryo for analysis. There are two important reasons for studying an embryo: 1) to avoid embryos with a hereditary disorder being implanted; and 2) to determine which genes play a role in embryonic development and implantation, so that fertility treatments can be improved. Supernumerary embryos can be used to refine and improve existing techniques used to examine DNA mutations, hereditary disorders or chromosomal disorders in embryos.

4. Embryonic stem cell research

A human embryo at five days old (the blastocyst) contains unique stem cells which, under certain conditions, can develop into any cell type in the human body, such as nerve cells, muscle cells, blood cells, egg cells, sperm cells, etc. The research seeks to discover whether these stem cells could be used in the future to replace damaged cells in diseases such as Parkinson's disease, heart failure and diabetes. Before this can be done safely, the cells must first be thoroughly studied.

5. Genome editing

This research investigates whether it is possible to modify the DNA in a human embryo in a safe and efficient manner. This could be useful on the one hand by preventing serious diseases in the future by correcting the gene responsible for that disease, and on the other hand by scientific research on genes which play a crucial role in early embryonic development, by switching off these genes and then studying the consequences for the further embryonic development.



INFORMATION REGARDING THE DONATION OF FROZEN SUPERNUMERARY EMBRYOS FOR SCIENTIFIC RESEARCH

- You may clarify in the agreement on the use of the supernumerary embryos the types of research for which the embryos may or may not be used.
- Your data will be processed in accordance with the European General Data Protection Regulation (GDPR). The confidentiality of the names and other personal data of you and your partner is strictly guaranteed. The research material will be encoded using 'pseudo-anonymisation', which means that your clinical data will also remain confidential.

The research has been commissioned by UZ Leuven and/or KU Leuven, and they are therefore responsible for the processing of data. If you have any questions about how we use your data or about exercising your right to inspect, correct or cancel any further processing, you can contact your doctor/researcher at any time at the following address: LUFC, UZ Leuven, Herestraat 49, 3000 Leuven, Belgium. If you subsequently have any further issues or wish to lodge a complaint, you can contact UZ Leuven at dpo@uzleuven.be (UZ Leuven studies) or KU Leuven at privacy@kuleuven.be (KU Leuven studies). Finally, you also have the right to submit a complaint on the way your data has been treated to the Belgian regulator responsible for enforcing the data protection legislation: Data Protection Authority/Gegevensbeschermingsautoriteit (GBA), Drukpersstraat 35, 1000 Brussels, Belgium. Tel. +32 2 274 48 00. E-mail: contact@apd-gba.be; Website: www.gegevensbeschermingsautoriteit.be.

- Every research protocol in which embryos may be used has received prior approval from the Ethics Committee research of UZ Leuven and KU Leuven and/or the Ethics Committee of the Faculty of Medicine (KU Leuven) and from the Federal Commission for Medical and Scientific Research on Embryos in vitro.

Participation in this research carries no financial benefits or additional costs. The prospective parents waive all intellectual and other rights associated with the scientific research on their embryos.

- You consent to any patent application for inventions which may ensue from the scientific research to which you have given your express consent, and you consciously waive any claim to payment or compensation.
- Scientific research sometimes involves genetic analysis of the studied embryos. The DNA sequences which may be obtained in this way as part of the research will be published in a secure (non-public) database (such as the European Genome Archive, dbGaP, etc.), which can only be consulted by approved, qualified researchers with the consent of the original authors. The DNA sequences are encoded in order to preserve confidentiality. Nonetheless, whilst unlikely, it is theoretically possible that another researcher could trace your identity on the basis of the research results. For this reason, you may indicate in the agreement on the use of the supernumerary embryos that you do not consent to the genetic analysis of the embryos and the associated publication of the (encoded) research data.
- In most cases, the selected research will be performed in the institution to which you donate the embryos for scientific research, namely LUFC. However, scientific research is increasingly carried out in collaboration with other Belgian university institutes, private-sector companies or foreign research institutes. In such cases, it is sometimes necessary to share certain personal data with external researchers; however, LUFC will never reveal your name or identity. Where scientific research is carried out in collaboration with other institutes or companies, it must still be approved by the ethics committee of the institute to which the embryos are donated and by the Federal Commission for Medical and Scientific Research on Embryos in vitro. In the agreement you will be able to decide whether the embryos you donate for scientific research may also be used in research that is carried out in collaboration with other Belgian research institutes, foreign research institutes and/or private-sector companies.
- You can withdraw your consent up to the point that the research starts. Withdrawal of your consent is valid at the request of either one of you. If one or both of you wish to withdraw your consent, you should



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INFORMATION REGARDING THE DONATION OF FROZEN SUPERNUMERARY EMBRYOS FOR SCIENTIFIC RESEARCH

communicate this in writing to Leuven University Fertility Centre, Contractenadministratie, UZ Leuven, Herestraat 49, 3000 Leuven, Belgium. On withdrawal of the consent, the embryos will be destroyed.



AGREEMENT ON STORING SUPERNUMERARY EMBRYOS

The Leuven University Fertility Centre,
UZ Leuven,
represented by
Professor Karen Peeraer

 and Ms
born on / /
and partner
born on / /
residing at
.....

Hereinafter referred to as LUFC, for the first part,
for the second part,

Hereinafter referred to as the prospective parents,

Hereby declare that they have agreed as follows:

1. Storage and storage period

The prospective parents declare that they are aware that all supernumerary embryos will be frozen, if the quality is sufficient and if all health conditions are met, at the LUFC with a view to fulfilling an existing or future desire to have children.

The LUFC will take due care in the freezing and preservation of the embryos. The LUFC is not liable for the loss of preserved embryos in cases of force majeure (such as fire, theft, power cuts or other external causes).

The prospective parents agree to first use the frozen embryos in a thawing cycle before new eggs are removed. They acknowledge that both partners must consent to a new implantation before any such medical procedure takes place.

The prospective parents declare that they have received all the necessary information regarding the circumstances and duration of the storage of their supernumerary embryos when the stated period comes to expire. By law, the storage period for supernumerary embryos frozen with a view to fulfilling a current or future desire to have children is five years. This period starts on the day on which the embryos are frozen. On the expiry of this period, the LUFC will carry out the instructions given by the prospective parents in the most recent agreement on storing of supernumerary embryos. On explicit request of the prospective parents or in special circumstances, the period can 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. In this case, the instruction indicated by the prospective parents in this agreement will be carried out.

It is also possible to make changes to the original agreement as regards the intended destination of the supernumerary embryos, unless the storage period for supernumerary frozen embryos has expired in the meantime. A request by the prospective parents 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.

If after signing the agreement the prospective parents are unable to agree on the destination of supernumerary embryos, the LUFC will take into account of their instruction as set out in the last agreement signed by both partners.



AGREEMENT ON STORING SUPERNUMERARY EMBRYOS

The prospective parents declare that they are aware that post mortem (after death) implantation of supernumerary embryos is not performed at the LUFC. If the prospective parents have chosen in the agreement to store their frozen embryos with a view to fulfilling a future desire to have children if one of the prospective parents passes away, there is the possibility of transferring frozen supernumerary embryos to a recognised centre for reproductive medicine (Type B). This centre will be responsible for further storage of the embryos under the agreed conditions.

II. Destination

The prospective parents declare that they have received sufficient explanation of the possible options for the destination of the supernumerary embryos.

- In selecting the option **‘to relinquish supernumerary frozen embryos for scientific research’**, the prospective parents expressly consent to the donation of their frozen supernumerary embryos to LUFC for the purpose of scientific research that has been approved by the Medical Ethics Committee of UZ Leuven and KU Leuven and/or the Medical Ethics Committee at the Faculty of Medicine (KU Leuven) and by the Federal Commission for Medical and Scientific Research on Embryos in vitro. This research is compliant with the Law of 11 May 2003 on in vitro research on embryos. The prospective parents declare that they have received, read and understood the ‘Information on relinquishing frozen supernumerary embryos for scientific research’.
- If the option **‘to relinquish supernumerary frozen embryos for training of laboratory staff’** is selected, the embryos may be used to teach certain techniques to the laboratory staff. The majority of techniques such as IVF, ICSI, embryo biopsy, freezing and thawing of embryos have become routine procedures. In order to be able to guarantee the quality of these procedures, it is important that we train the laboratory staff to carry out the technological procedures to the highest possible standard and to learn to constantly improve the existing procedures.
- If the option **‘to destroy supernumerary frozen embryos’** is selected, LUFC will destroy the supernumerary embryos without any interventions other than those needed for the destruction.

III. Cost

An estimate of the costs can be found at www.uzleuven.be/kostenraming under Gynaecologie en Verloskunde.



AGREEMENT ON STORING SUPERNUMERARY EMBRYOS

IV. Agreement

The prospective parents hereby declare that they have taken the following decision relating to the destination of their frozen supernumerary embryos. They wish to:

Destination of supernumerary frozen embryos

Indicate your decision at A, B and C:

A. On the expiry of the stated storage period (thick one box only at

- relinquish these embryos for: (both options may be selected at)
 - scientific research*
 - training of laboratory staff*
- destroy these embryos

B. In the event of separation or divorce, if one of the prospective parents is permanently incapable of making decisions or if the prospective parents have a difference of opinion that cannot be resolved (thick one box only at

- relinquish these embryos for: (both options may be selected at)
 - scientific research*
 - training of laboratory staff*
- destroy these embryos

C. If one of the prospective parents dies (thick one box only at

- relinquish these embryos for: (both options may be selected at)
 - scientific research*
 - training of laboratory staff*
- to destroy these embryos
- store these embryos with a view to the later fulfilment of child wish (post-mortem implantation by means of transportation to a recognised centre for reproductive medicine (type B)).

* If the embryos will not suitable for scientific research or training, or an abundant number of embryos will be available for scientific research or training, these embryos will be destroyed.

V. If the choice is **to relinquish the embryos for scientific research**, the prospective parents can indicate below the categories of research for which their embryos may be used. The prospective parents declare that their embryos may be used for research in:

- all research fields: see below and the additional explanation in 'Information regarding donation of frozen supernumerary embryos for scientific research':
 1. In vitro fertilisation and freezing techniques
 2. Embryonic development and implantation of the embryo in the uterus
 3. (Epi)genetic status of the embryo
 4. Embryonic stem cell research
 5. Genome editing
- all research fields except for those numbered (please enter as appropriate):



AGREEMENT ON STORING SUPERNUMERARY EMBRYOS

The consent for scientific research can be withdrawn unilaterally by one of the two prospective parents (the embryos will then be destroyed). However, if an irreconcilable difference of opinion should arise between the partners regarding one of the other uses, the most recent joint decision will apply.

The prospective parents have understood from the 'Information on relinquishing of supernumerary embryos for scientific research' that scientific research sometimes involves genetic analysis of the studied embryos. The data obtained in this way during the research will be published in genetic (non-public) databases (such as the European Genome Archive, dbGaP, etc.), which can only be consulted by approved, qualified researchers with the consent of the original authors.

 The prospective parents

- give consent for genetic analysis and the sharing of genetic information via databases
- do not give consent for genetic analysis and the sharing of genetic information via databases

In most cases, the selected research will be performed in the institution to which you donate the embryos for scientific research. However, scientific research is increasingly carried out in collaboration with other Belgian university institutes, private-sector companies or foreign research institutes. In such cases, it is sometimes necessary to share certain personal data with external researchers; however, LUFC will never reveal your name or identity. In these cases, the research must still be approved by the ethics committee of the institute to which the embryos are donated and by the Federal Commission for Medical and Scientific Research on Embryos in vitro.

 The prospective parents declare that the embryos they are donating for scientific research may also be used in research that is carried out in collaboration with (several options are possible):

- a research institute within Europe
- a research institute outside Europe
- a private-sector company

The prospective parents

- give consent for their personal data to be shared with other researchers
- do not give consent for their personal data to be shared with other researchers



AGREEMENT ON STORING SUPERNUMERARY EMBRYOS

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

Name Madam

Name Partner

.....

.....

.....

.....

born on / /

born on / /

Professor Karen Peeraer
Administrator Tissue Bank LUFC


read and approved
signature Ms


read and approved
signature Partner

Attention! You can only start a cycle once the LUFC is in possession of this fully completed, dated and signed form.

Please complete and sign this agreement and return it to Leuvens Universitair Fertiliteitscentrum, 'Contractenadministratie', UZ Leuven, Herestraat 49, 3000 Leuven, Belgium, or contractenLUFC@uzleuven.be.