

THE CENTER FOR ADVANCED REPRODUCTIVE SERVICES (CARS) (The Center)

CONSENT FOR CRYOPRESERVATION AND STORAGE OF EMBRYOS

Gender Partner #1 Last Name (Surname): _____ Partner #1 First Name: _____

Partner #1 ID# _____ Partner #1 Gender M/F (Circle One)

Partner #2 Last Name (Surname): _____ Partner #2 First Name: _____

Partner #2 ID # _____ Partner #2 Gender M/F (Circle One)

Address: _____

Phone Number: _____

We (I), the undersigned, request, authorize and consent to the cryopreservation (freezing) and/or storage of embryos by The Center for Advanced Reproductive Services, PC (The Center), and, as appropriate, its employees, contractors, and consultants and authorized agents.

We (I) understand that there are other options available to us to help us have a child. These may include but are not limited to adoption or treatments including such techniques as surgery, ovulation induction and sperm or egg donation or egg freezing. We (I) have had the opportunity to discuss these options as well as others with our (my) physician. In an attempt to have a child, we (I) now elect to utilize in vitro fertilization and embryo transfer with embryo cryopreservation at The Center For Advanced Reproductive Services.

Source Of Eggs And Sperm For This Procedure:

Egg Source: For the purpose of providing the eggs in this procedure, listed below is the designated egg source for performing this procedure.

Egg Source: _____ (For Anonymous Egg Donors (AED) use donor # where applicable otherwise use female's name)

Sperm Source(s): For the purpose of fertilizing the eggs in this procedure, listed below is (are) the designated source of sperm for performing this procedure.

Sperm source (1): _____ If Donor Sperm, list sperm bank and donor number, otherwise list male's name.

Sperm source (2): _____ (in the case of same sex men splitting eggs or couples using both partner and donor sperm).

We (I) understand and agree that in most circumstances only embryos from a single egg and sperm source will be transferred during the embryo transfer (that is, embryos from mixed sources may not be transferred at the same time). The choice of which embryos to transfer is usually based on embryo quality and the best medical judgment of the medical team in consultation with us (me).

Description of the Procedure:

Cryopreservation (Freezing) of embryos is a laboratory procedure that is performed when there are good quality viable embryos produced during an IVF cycle that cannot all be transferred to the uterus of the woman who will carry the pregnancy during that IVF cycle. This may occur for the following reasons:

1. If numerous eggs are retrieved during the in vitro fertilization (IVF) cycle, the number of eggs exposed to sperm will be decided by you and your doctor. If you elect to expose most or all of your eggs to sperm in order to develop as many embryos as possible, any good quality, viable embryos not transferred to the uterus will be frozen (cryopreserved) and stored for future use.

2. If you have undergone IVF for the purpose of fertility preservation based on a medical condition (for example, prior to chemotherapy for cancer) or for a condition or situation where an embryo transfer is not possible or would not be safe (for example, ovarian hyperstimulation syndrome (OHSS)) only good quality embryos with a high likelihood of surviving the freeze/thaw process will be frozen and stored for future use.
3. In the case of a natural disaster, emergency or other situation where the laboratory, staff or facility or woman who will carry the pregnancy is not available for an embryo transfer during the initial IVF cycle, good quality embryos with a high likelihood of surviving the freeze/thaw process will be frozen and stored for future use.

Laboratory Aspects. The embryos are frozen using mechanical equipment using cryoprotectant agents (chemicals that act as antifreeze) and stored at ultralow temperatures to maximize their viability for long periods of time.

We (I) understand that execution of this consent does not guarantee that embryos will be cryopreserved and that the decision about freezing (cryopreserving) embryos usually cannot be made in advance. The number of embryos frozen will be at the discretion of The Center staff, based upon the embryo quality and our (my) choice in consultation with our (my) physician. We (I) understand that we (I) will be notified if embryos are cryopreserved.

Testing and Screening. We (I) understand and agree that the Center medical team may require additional blood tests and a sample of my blood plasma, at their discretion, for the safe storage of the frozen embryos and that the embryos will be stored with embryos of similar infectious disease status.

How can the Frozen Embryos be used?

If a pregnancy does not occur as a result of the initial embryo transfer during the fresh IVF cycle, if we (I) have a miscarriage, or if a successful pregnancy does occur but we (I) subsequently desire another child, the frozen embryos will be available to us (me) for thawing and transfer during a subsequent menstrual cycle. This procedure may be repeated until all the frozen embryos have been utilized. We (I) understand and agree that it is a policy of The Center to store our (my) embryos for a maximum time period of five (5) years.

At any time during the storage of our (my) embryos, when our (my) treatment at The Center is completed, at the end of five years of storage or if The Center closes (whichever comes first) we (I) understand that we (I) have several options regarding our (my) frozen embryos in storage at The Center including:

1. Donation of the embryos to another couple or woman for their (her) own attempts at pregnancy.
2. Disposal of the embryos according to American Society for Reproductive Medicine (ASRM) Ethical Guidelines.
3. Transfer of the cryopreserved embryos from the Laboratory at the Center to another fertility center, long term storage facility or research facility.

We (I) understand that each of these options requires execution of an additional written consent form signed by both of us (me) at the time that this option is exercised.

Limits to the Success of Embryo Cryopreservation (Freezing) and Potential Risks of Freezing and Storage:

1. There may be no extra good quality embryos available to freeze.
2. Not all embryos that are frozen and thawed will survive. On average, about 70 % of embryos survive the freezing and thawing process, so the number of embryos that are viable after thawing may be less than the number of embryos frozen.
3. It is possible that none of the embryos will survive the freezing and thawing process. Embryos may survive the thawing process but may not result in a pregnancy when transferred. There is no guarantee that the transfer of frozen embryos will result in a successful pregnancy. We (I) have discussed The Center's pregnancy rates for frozen embryo transfers with our (my) doctor.
4. A pregnancy may result but a pregnancy may not be normal.

Laboratory Procedures. Both the cryopreservation and storage procedures involve the use of mechanical and/or electrical equipment. The Center will take reasonable measures to maintain and monitor this equipment. However, despite their best efforts, equipment failure may result in the damage or loss of one or more of the embryos. We (I) understand and agree that The Center shall be responsible only for acts of negligence on its part and the part of its employees, contractors, and consultants.

The growth of human embryos requires a source of protein. The Center may use a protein product derived from human blood. The manufacturing process involves several purification steps including heat treatment, treatment with detergents, and treatment with ethanol which is thought to render these products free of infectious disease agents such as the hepatitis

virus and the virus responsible for AIDS. These blood products are used to treat up to 1 million patients every year for shock, burns, and many other medical emergencies. These products are thought to be extremely safe due to the screening and purification procedures utilized; however, there is a theoretical risk that the agents responsible for causing various infectious diseases could still be transmitted by utilization of these blood derived products.

Non-Viable Embryos. We (I) understand that some non-viable embryos may be used as a teaching aide for laboratory personnel before being discarded. We (I) understand that non-viable embryos will be discarded according to ASRM Ethical Guidelines.

Pregnancy Outcome. While we will sign an additional consent to utilize these embryos which will describe the risks in more detail, we (I) also understand that it does not appear that the freezing and thawing of embryos increases our (my) risk of having a child with a birth defect above the incidence observed in the spontaneously conceiving population.

Conditions of Continued Storage of Cryopreserved Embryos:

Embryos that are cryopreserved (frozen) may be in storage at the Center for extended periods of time (up to 5 years). Therefore, the conditions under which storage will be continued and what should be done with the embryos if something were to happen to you or your partner (if applicable) must be defined from the beginning.

What should be done with the cryopreserved embryos in each of the following cases?

We (I) understand that any future use of these embryos will require the signature of the same individuals who sign this consent even if we are no longer a couple, except as provided below. If one member of the couple who signed the original consent has died, then a death certificate must be provided.

In the event of death:

1. We (I) understand, agree and consent that if **one** of us dies (PLEASE CHECK ONE AND BOTH PARTNERS SHOULD INITIAL):

- ☐ The disposition of the embryos will be left to the surviving partner.
- ☐ The embryos will be discarded according to American Society for Reproductive Medicine Ethical Guidelines.

Partner #1 Initials _____

Partner #2 Initials _____

2. We (I) understand, agree and consent that if **both** of us dies (PLEASE CHECK ONE AND BOTH PARTNERS SHOULD INITIAL):

- ☐ The embryos will be discarded according to American Society for Reproductive Medicine Ethical Guidelines unless otherwise provided for according to our will.
- ☐ The embryos will be transported to a long term storage facility at the expense of our (my) estate and that if that is not possible the embryos will be discarded according to American Society for Reproductive Medicine Ethical Guidelines.

Partner #1 Initials _____

Partner #2 Initials _____

3. I understand that if I am single, and I die without a partner then

- ☐ The embryos will be discarded according to American Society for Reproductive Medicine Ethical Guidelines.

Initial: _____

In the event that we divorce or our relationship ends:

We (I) understand, agree and consent that if ***we divorce*** or our relationship ends (PLEASE CHECK ONE AND BOTH PARTNERS SHOULD INITIAL):

- ☐ Custodial decisions and expenses will be left to the following partner (Please write in the name of the partner). Please note that custodial decisions refer to ongoing storage logistics and not to use of the embryos. In all cases, consents to use, donate or discard the embryos will require the signature of the same individuals who sign this consent

(Write in Partner Name)

Write Designee Phone Number and Address:

Phone: _____

Partner #1 Initials _____

Partner #2 Initials _____

- ☐ The embryos will be discarded according to American Society for Reproductive Medicine Ethical Guidelines.

Partner #1 Initials _____

Partner #2 Initials _____

Fees for Storage and Billing Policies:

The first year of storage of the frozen embryos is included in the cryopreservation fee. At the end of the first year, you will be billed quarterly, in advance, for continued storage of the embryos, up to the five year maximum storage period.

The billing and collection process is described below:

- The practice will send out a letter thirty to sixty (30—60) days prior to the first storage billing as a reminder that billing for storage will begin and summarizing the storage options.
- After the first year of storage, embryo storage fees are billed quarterly; the quarterly billing will be sent in the first quarter following the one year anniversary date.
- All embryo storage payments are due within thirty (30) days of receiving a statement.
- After 30 days, all unpaid balances roll into the Center's collections module and a first collection letter will be sent.
- Thirty (30) days later, a second collection letter will be sent notifying you that payment is due or the matter will be referred to a collection agency. Thirty (30) days after the second letter, if no payment is received the matter will be referred to a collection agency.
- All accounts with two (2) unpaid quarters of storage billing (consecutive or not), will be automatically sent to collections.

We (I) understand that if two consecutive quarters of embryo storage billing roll into the Center's collections module all subsequent quarterly embryo storage billings will go directly to collections until all past balances have been paid. We (I) understand that all accounts must be kept current in order to undergo subsequent treatment or have access to the samples. If storage fees are entirely unpaid after one year in collection, the embryos will be considered abandoned and will be discarded according to ASRM Guidelines.

For more information on all of these options please go to The Center's website, www.uconnfertility.com > Our Programs and Services > Embryo Options.

We (I) understand it is our (my) obligation to notify The Center of any change of address, and that if we (I) do not do so The Center is not liable for its inability to contact or bill us (me). If we (I) fail to do so or cannot be reached or do not respond to correspondence received from the Center for one year, we (I) understand and agree that the embryos will be considered abandoned and will be discarded by the Center according to American Society for Reproductive Medicine Ethical Guidelines.

We (I) understand that we (I) may store our frozen embryos on site at The Center for up to 5 years in anticipation of utilizing them for subsequent fertility treatments. However, we (I) understand that The Center is not equipped to serve as a long term storage facility. After 5 years we (I) agree to review our (my) options which may include, moving the embryos to a long term storage facility, donating the embryos to another couple, donating the embryos to research or discarding the embryos. ***We (I) understand that none of the aforementioned options can be exercised without our (my) informed written consent.***

We (I) acknowledge that, at any time during the five year maximum storage period or at the end thereof, we (I) can execute the appropriate consents to exercise any of the options listed above including moving the embryos to a long term storage facility, donating the embryos to another couple, donating the embryos to research or discarding the embryos **and that all storage fees will continue to accrue until The Center receives a properly executed consent for this procedure.**

Additional Considerations:

We (I) understand that consents for future donation, disposal, transfer out or utilization (subsequent thaw cycle) must be signed by both individuals who signed this Cryopreservation consent, unless an applicable court decree or death of one of us supersedes it or I am a single person. We (I) understand and agree that, in any situation where there is a conflict between the parties, the embryos will be moved to a long term storage facility at our (my) expense.

Confidentiality. We (I) understand the confidentiality of medical records, including any photographs, X-rays or recordings, will be maintained in accordance with applicable state and federal laws. We (I) may request our records be released to other physicians. Data from our (my) ART procedure will also be provided to the Centers for Disease Control and Prevention (CDC). The 1992 Fertility Clinic Success Rate and Certification Act requires that CDC collect data on all assisted reproductive technology cycles performed in the United States annually and report success rates using these data. Because sensitive information will be collected on you, CDC applied for and received an "assurance of confidentiality" for this project under the provisions of the Public Health Service Act, Section 308(d). This means that any information that CDC has that identifies you will not be disclosed to anyone else without your consent.

Legal Actions. We (I) understand, agree and consent that any legal actions that are required as a result of disagreements between the parties about the disposition or use of sperm, eggs or embryos will be at our (my) expense.

We (I) expect this procedure to be performed with not less than the customary standard of care. We (I) understand the risks and benefits as outlined, and further understand and agree that The Center shall be responsible only for acts of negligence on its part and the part of its employees, contractors, and consultants and authorized agents.

Embryo Cryopreservation and Storage has been explained to us (me) by our (my) doctor, together with the known risks. We (I) understand the explanation that has been given to us (me). We (I) have had the opportunity to ask questions and those questions have been answered to our (my) satisfaction. Any further questions we (I) might have may be addressed to The Center staff or IVF/ET Program Director, Dr. John Nulsen at 844-467-3483. We (I) acknowledge that IVF/ET and Embryo Cryopreservation is being performed at our (my) request and with our (my) consent.

We (I) represent, agree and acknowledge that we (I) are (am) not married to individuals who are not parties to the informed consents signed as part of these procedures.

____/____/____ _____ _____
Date Partner #1 Signature Print Name

Time: _____AM/PM

____/____/____ _____ _____
Date Witnessed By: Print Name

Time: _____AM/PM

____/____/____ _____ _____
Date Partner #2 Signature Print Name

Time: _____AM/PM

____/____/____ _____ _____
Date Witnessed By: Print Name

Time: _____AM/PM

*** If no partner, write N/A

Note: Each Signature Must Be Witnessed Separately

Physician Signature:

This consent has been discussed with both partners, where applicable.

____/____/____ _____
Date Physician Signature

Time: _____AM/PM

- ☐ **Important:** Please check here if a notarized version of this signature page is attached. (Note: it *is* acceptable for one member of the couple to sign in person in the office and the other to sign notarized version).

Initials of CARS Representative _____