Consent for Ovarian Stimulation, Oocyte (Egg) Retrieval, Oocyte Cryopreservation, Storage and Disposition

Book Number ________________________

Patient Name (Please print):__________________________________________________________

Legal Guardian (Please print, if applicable): __________________________________________

Patient, IVFNE eIVF Number: ________________________________

Partner Name (Please print, if applicable): ____________________________________________

Partner, IVFNE eIVF Number: ________________________________

Please read the following consent carefully. If you do not understand the information provided, please speak with your treating physician or nurse. After reading this consent, you will be asked to make several decisions regarding the elements of treatment you agree to undertake.

Patient and Partner (if applicable) must present PHOTO IDs and sign in the presence of an authorized representative of IVF New England (IVFNE).

This consent must be signed by the Patient and Partner (if applicable) at each signature line noted for Patient and Partner.

All sections must be signed by Patient and Partner (if applicable). If you and/or your partner are unable to sign the consent in the presence of an authorized IVFNE representative, the consent must be notarized including the Notarization Form attached to this consent and returned to IVFNE. You should keep the Consent for Treatment book for your records.

Introduction

The following information will describe a procedure for the cryopreservation (freezing) of human eggs for the purpose of preserving the patient’s fertility through the provision of eggs that can be thawed for later reproduction. Your physician will review this information with you and answer your questions.

The following steps are involved in the cryopreservation of eggs: ovarian stimulation and monitoring, egg retrieval, egg cryopreservation and storage. Please refer to the corresponding sections in the...
Consent for Treatment book: Medications for IVF Treatment, Trans-vaginal Oocyte Retrieval, Oocyte Cryopreservation, and Ovarian Hyper-stimulation Syndrome. You are a candidate for this protocol because you desire to conserve your reproductive potential by freezing your eggs for potential future use to become pregnant.

Indications for oocyte cryopreservation include the following:

a. Electively delay childbearing  
b. Limiting the number of eggs to be inseminated or used for treatment  
c. Anticipation of medical treatment that will negatively affect ovarian and reproductive functions  
d. Donation of eggs to another individual

The process of freezing eggs for the conservation of fertility is a relatively new technique among the assisted reproductive technologies and is evolving. IVFNE uses protocols, methods and instrumentation that have been validated in other centers as well as our own center.

PLEASE CIRCLE YES OR NO AND/OR SIGN EACH SECTION below to indicate your decisions and understanding of the elements of Oocyte Cryopreservation you agree to undertake in your upcoming treatment cycle.

Yes No Oocyte development and monitoring  
Stimulation of oocyte development requires the use of injectable medication to induce maturation of multiple follicles. Monitoring of this process involves serial ultrasound examinations and blood tests to assess potential oocyte maturation and female hormone status. (Please see section on Medications for IVF Treatment in the Consent for Treatment book)

Trans-vaginal Oocyte (Egg) Retrieval  
Retrieval of eggs through ultrasound-guided aspiration is performed under IV-sedation or other forms of anesthesia. A special needle is used to pass through the vaginal wall in order to enter the ovarian follicles.

Yes No Trans-vaginal aspiration of my ovarian follicles and isolation of my oocytes at a time to be determined by my physician.

and

Yes No If during the course of performing the retrieval or at any time during my cycle, my/our physician determines that an ovarian cyst(s), that may or may not contain oocytes, is present; I/we desire that the cyst(s) shall also be aspirated.

__________________________________  __________________________________
Patient signature  

OR

__________________________________
Legal Guardian signature

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Risks of Procedure
I/we have been fully advised of the risks and benefits of each of the procedures indicated above and have been informed of the available alternatives and risks and benefits of such alternatives. This information, which is described in the Consent for Treatment book, has been supplemented by my/our consultation with my/our physician and medical team.

________________________________________
Patient signature

OR

________________________________________
Legal Guardian signature

Egg cryopreservation

The process of cryopreservation of embryos has been used for many years. In contrast, cryopreservation of eggs by a process called vitrification, is a relatively new application.

At present, there is very little information on whether or not conception following egg cryopreservation carries a genetic risk to the infant. If pregnancy occurs following the use of a cryopreserved egg, routine prenatal screening is recommended and more definitive testing by amniocentesis or chorionic villus sampling (CVS) may be considered. Your obstetrician will discuss the risks and benefits of these diagnostic procedures with you. If pregnancy occurs, the delivery of a child may not occur due to miscarriage, ectopic pregnancy or other complications of pregnancy or delivery.

Based upon the discussion with your physician that addressed the risks, benefits and alternatives to it, cryopreservation of eggs has been mutually chosen by you and your physician.

AUTHORIZATION TO CRYOPRESERVE EGGS

Eggs that have been determined to be viable and mature by the Embryology Laboratory will undergo the cryopreservation process according to my directions as follows (please indicate “yes” or “no” option)

Yes  No  Cryopreserve all viable and mature eggs for future attempts to conceive.

OR

Yes  No  Cryopreserve viable eggs retrieved during this stimulation cycle as follows:

___  Number of eggs to be inseminated

___  Number of eggs to be cryopreserved
Storage

As the patient, you have full authority over the disposition and use of your cryopreserved eggs. IVFNE, however, is not obligated to proceed with the transfer of embryos made using cryopreserved eggs if, on the basis of any new scientific or medical evidence or information, it is their opinion that the risks outweigh the benefits.

You have the option to store cryopreserved eggs at IVFNE. There is an initial cost to cryopreserve eggs plus a monthly storage fee (Please refer to the Fees for Oocyte Cryopreservation and Storage included with this consent). There is an additional fee to thaw and inseminate the eggs and transfer embryos produced from cryopreserved eggs. IVFNE reserves the right to terminate their participation in the cryopreservation and storage of eggs. In this unlikely event, all reasonable efforts will be made to arrange for disposition of eggs remaining in storage according to your desires.

There may be agencies that can facilitate the donation of cryopreserved eggs to another person or couple. Should this option be chosen, you will be provided with the names of agencies that may specialize in this area. However, there may be federal and state mandated screening and testing requirements for potential donation of cryopreserved eggs that will need to be obtained at the time of egg retrieval and prior to donation.

AUTHORIZATION TO STORE CRYOPRESERVED EGGS

Please circle YES or NO and sign below to acknowledge your consent for storage of your cryopreserved eggs at IVFNE and your understanding of the Fees for oocyte cryopreservation and storage and disposition policies at IVFNE.

Yes No

Storage at IVF New England according to the conditions stated in the Fees for Oocyte Cryopreservation and Storage included with this consent.

Disposition of Cryopreserved Oocytes (Eggs): Any disposition of oocytes requires the written authorization of the patient or legal guardian. If the eggs are to be inseminated with sperm from a partner thus creating embryos for transfer or other disposition (e.g cryopreservation), the signature from the partner is also required in addition to any other applicable consent and disposition forms.
I understand and agree that in the event of death or incapacitation, the disposition of any cryopreserved oocytes shall be determined by applicable law, a court order or as designated in my will. If a surviving partner, friends or family members wish to conceive with these oocytes after your death, a legal document indicating this intent will be required.

I understand that IVF New England will maintain cryopreserved oocytes according to the Fees for Oocyte Cryopreservation and Storage policy included with this consent form. Cryopreserved oocytes will be maintained until specific directives and authorization for those directives are provided by me. When I have decided on the method of disposition of my oocytes, I will need to sign the IVFNE consent specific to our choice of disposition. All storage fees will apply until such time that this consent is provided to IVFNE and approved by the Laboratory Manager. IVF New England reserves the right at its sole discretion to make decisions regarding the final disposition of cryopreserved oocytes if fee obligations are not met.

By signing below, I understand and agree to the terms of the Fees for Oocyte Cryopreservation and Storage policy and to the conditions stated above regarding the disposition of my cryopreserved oocytes.

______________________________
Patient signature

OR

______________________________
Legal Guardian signature

Patient acknowledgement

Mechanical or power failures can occur at any point in the freezing process that could result in the loss of the future viability of the eggs. Similarly, once the eggs are in storage, acts of nature (fire, earthquake, prolonged loss of power, etc.) or terrorism could result in the loss of the cryopreserved eggs. IVFNE is not liable for the loss of frozen eggs caused by such events.

I understand that there is no guarantee regarding the number of eggs that will be frozen, or that the eggs will be normal or will be mature. There is no guarantee that the eggs, after freezing and thawing, can be utilized in the future to establish a pregnancy, or that I will become pregnant and deliver a baby using my cryopreserved eggs. I understand that the techniques used to freeze and thaw eggs may reduce the chances for a clinical pregnancy or live birth.

I understand that egg cryopreservation is a relatively new procedure. Although current data are reassuring, at this point in time, all of the risks of the procedure to potential offspring are not known.

I understand that no guarantees can be made regarding the survival of eggs during the thawing process, or the outcome of fertilization, implantation and subsequent pregnancy outcome.
If I choose to transfer my cryopreserved eggs to another storage facility, I understand that I have full and sole responsibility for the transport and disposition of my cryopreserved eggs and hereby release IVFNE from any and all responsibility relating to the transport of my cryopreserved eggs.

As required by the 1992 Fertility Clinic Success Rate and Certification Act, data from the assisted reproductive technology procedures may be provided to the Centers for Disease Control (CDC) through an intermediary agent, the Society for Assisted Reproductive Technology (SART). Because of the sensitive nature of the information collected and transmitted, the CDC received an “assurance of confidentiality” under the provisions of the Public Health Service Action. Any information that the CDC has that identifies me will not be disclosed to anyone without my consent.

I agree to release and hold harmless IVFNE, its trustees, directors, officers, shareholders, employees, servants, agents, affiliates, management companies and representatives for any and all damages, expenses, causes of action, suits and claims made or initiated with respect to the legal custody, rights and/or physical defect or abnormality of the egg as a result of ovarian stimulation, the egg retrieval egg cryopreservation and storage to the extent that such liabilities are not attributable to the negligence or willful misconduct of IVFNE and with respect to any claimed emotional injury or cost arising out of my participation in the above mentioned services.

I have been provided with sufficient information about assisted reproductive technology and cryopreservation methods as well as the risks, benefits and alternatives for egg cryopreservation and storage. I have had the opportunity to consult with my physician and have been provided with supplemental written information to support these discussions. My physician has answered any and all questions I have posed to my satisfaction.

I have read this document in its entirety and have had ample time to reach my decision free from pressure and coercion and to proceed with my participation in the assisted reproductive services described above.

____________________________________                     ______________________
Patient signature                                      Partner signature (if applicable)
Date: _____/_______/___________                      Date: _____/_______/___________
        Month   Day      Year                          Month   Day      Year

OR

____________________________________
Legal Guardian signature
Date: _____/_______/___________
        Month   Day      Year
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PHYSICIAN ATTESTATION

All parties indicated above have been counseled by me and other members of the care team regarding the risks and benefits of the relevant treatment options, including non-treatment. All parties appeared capable of understanding (age-appropriate understanding in the case of a minor requiring Guardian consent) the information presented.

Physician Signature: ________________________________  Date: _____/_____/__________
Notarization Form

This form must be completed for consents signed outside the Practice

Patient name (please print): _____________________________________________________

State of 
County of _________________

I certify that I know or have satisfactory evidence that ___________________________ is the person who appeared before me, and said person acknowledged that he/she signed this instrument and acknowledged it to be his/her free and voluntary act for the uses and purposes mentioned in the instrument.

Dated ___________________  
Notary Signature

____________________________________
Title

My appointment expires: __________

Partner name (please print if applicable): ___________________________________________

State of 
County of _________________

I certify that I know or have satisfactory evidence that ___________________________ is the person who appeared before me, and said person acknowledged that he/she signed this instrument and acknowledged it to be his/her free and voluntary act for the uses and purposes mentioned in the instrument.

Dated ___________________  
Notary Signature

____________________________________
Title

My appointment expires: __________