Assisted Reproduction: In Vitro Fertilization, Intracytoplasmic Sperm Injection, Assisted Hatching, and Embryo Cryopreservation/Disposition Consent

Book Number ________________________

Patient Name (Please print): ___________________________________________________

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 IVF treatment you are agree to undertake in your upcoming IVF treatment cycle.

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.

I/We hereby acknowledge that I/we have received the Consent for Treatment book and have been given ample opportunity to review it. I/We have read and understand the information provided in the Assisted Reproduction booklet. I/We have conferred with my/our physician and medical team, during which time we have discussed: (1) the risks and benefits of ART treatment; (2) my/our individual medical circumstances; and, (3) options including non-treatment and/or adoption. Any questions I/we had were answered.

Unless treatment decisions change, this signed consent form will be considered valid for one year. If there are changes to these treatment decisions, a new consent form must be signed.

__________________________________                        __________
Patient signature                        Partner signature (if applicable)

Revised October 2014
Components of IVF Treatment

Please CIRCLE YES OR NO AND SIGN EACH SECTION below to indicate your decisions regarding the elements of IVF treatment you agree to undertake in your upcoming IVF treatment cycle.

In-Vitro Fertilization:
Oocyte (egg) Development and Monitoring
Stimulation of ovaries to induce maturation of multiple follicles with injectable medications (Please see section on Medications for IVF Treatment in the Consent for Treatment book). Serial ultrasound examinations and blood tests to monitor growth and development of follicles and female hormone status.

Yes  No  Stimulated Cycle Oocyte (egg) development and monitoring

___________________________________                     __________________________________
Patient signature                           Partner signature (if applicable)

Transvaginal 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  Transvaginal aspiration of my ovarian follicles and isolation of my oocytes (eggs) 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                           Partner signature (if applicable)

Sperm Source:
Production of semen specimen or acquisition of sperm of sufficient quality or quantity to inseminate retrieved eggs

Yes  No  Male Partner
Yes  No  Anonymous Donor
Yes  No  Known Donor (Full name): ____________________________________________ (MPI #) ________

___________________________________                     __________________________________
Patient signature                           Partner signature (if applicable)
**Insemination of oocytes:** Placing egg(s) and sperm together in a special culture to allow fertilization

Yes  No  I/we agree to attempt to inseminate all viable oocytes

OR

Yes  No  If all viable oocytes (eggs) are not to be inseminated, I/we agree to the insemination of _____ oocytes and discarding the remainder not inseminated

OR

Yes  No  If all viable oocytes (eggs) are not to be inseminated, I/we agree to the insemination of _____ oocytes and cryopreserving the remainder not inseminated

(Separate consent for Ovarian Stimulation, Oocyte Retrieval, Oocyte Cryopreservation, Storage and Disposition is required)

___________________________  __________________________________
Patient signature                     Partner signature (if applicable)

**Yes  No  Intracytoplasmic Sperm Injection** - To ensure that you have the best options available for pregnancy in your IVF cycle, the IVFNE medical team recommends that you circle “Yes” and sign here for Intracytoplasmic Sperm Injection (ICSI). In most circumstances, the medical indications for the use of ICSI are anticipated and its indications for use in your care will have been discussed with you. However, at times, based on the embryology laboratory assessment of the sperm and/or eggs the day of the egg retrieval or day after, the unanticipated use of ICSI to aid fertilization may be warranted. If the ICSI consent has not been circled “Yes” and signed, the addition of ICSI to improve your chances of pregnancy in the cycle cannot be done.

___________________________  __________________________________
Patient signature                     Partner signature (if applicable)

**Yes  No  Assisted Hatching** - To ensure that you have the best options available for pregnancy in your IVF cycle, the IVFNE medical team recommends that you circle “Yes” and sign here for Assisted Hatching (AH). In most circumstances, the medical indications for the use of AH are anticipated and its indications for use in your care will have been discussed with you. However, at times, based on the embryology laboratory view of the embryos the day of the embryo transfer, the unanticipated use of AH to aid implantation may be warranted. If the AH consent has not been circled “Yes” and signed, the addition of the AH to improve your chances of pregnancy in the cycle cannot be done.

___________________________  __________________________________
Patient signature                     Partner signature (if applicable)
Pre-implantation Genetic Diagnosis (PGD)
PGD involves biopsy of an embryo to determine if the embryo is affected by the genetic condition of concern. There are generally three categories of testing. Full explanation of testing is described in the Consent for Treatment book and outlined in the Consent for Pre-implantation Genetic Diagnosis, Embryo Biopsy and Embryo Disposition.

Please circle “yes” to all that are applicable:

Yes  No  Testing for single gene mutation
Yes  No  Testing for structural chromosomal anomaly
Yes  No  Testing for chromosome copy number

________________________________________          ________________________________________
Patient signature  Partner signature (if applicable)

Embryo Transfer
Placing developing embryo(s) into the uterus by means of a catheter (small tube) inserted through the cervix

Multiple gestations, including twin pregnancies and particularly those involving three or more fetuses, pose significant potential medical risks to the patient, the pregnancy, and any resulting offspring. There is considerable evidence that the rise in multiple births over the last two decades is due in large part to assisted reproductive technologies.

Yes  No  I/we agree to embryo transfer. After discussion with the physician I/we will determine the appropriate number of embryos to be transferred consistent with current Society for Assisted Reproductive Technology/ American Society for Reproductive Medicine (SART/ASRM) guidelines and professional standards of care.

________________________________________          ________________________________________
Patient signature  Partner signature (if applicable)

Risks of Procedure
I/we have been fully advised of the risks and benefits of each of the procedures indicated above, as well as ART generally, 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 booklet, has been supplemented by my/our consultation with my/our physician and medical team. I/we understand that there are risks associated with pregnancy and especially multiple pregnancies, should it occur, and that my/our obstetrician will provide my/our treatment during any such pregnancy. I/we understand that there is no pregnancy guarantee.

________________________________________          ________________________________________
Patient signature  Partner signature (if applicable)
Yes  No  Quality Control for In Vitro Fertilization and Embryo Culture (as described in the Consent for Treatment handbook)

Quality control in the IVF Laboratory is important. Sometimes immature or unfertilized eggs, sperm or abnormal embryos (abnormally fertilized eggs or embryos whose lack of development indicates they are not of sufficient quality to be transferred) or the discarded fluids and media from their culture can be used for quality control. You are being asked to allow IVF New England to use this material for quality control purposes before being discarded in accordance with normal laboratory procedures and applicable laws. None of this material will be utilized to establish a pregnancy or to create a cell line for research purposes.

________________________________________          _______________________
Patient signature                      Partner signature (if applicable)

HIV (Human Immunodeficiency Virus) Test
I/We have been counseled as to the need for, and limitations of, testing for the HIV virus (the virus that causes AIDS). In signing this consent form, I/we consent to be tested for the HIV virus and to the release of the results to my/our physician. I/we also agree to inform the results of the test to my partner.

________________________________________
Patient signature                      Partner signature (if applicable)

Yes  No  Embryo Cryopreservation of viable, high quality embryos (if any) not transferred. I/We understand that to date, there are no known effects from long-term storage of cryopreserved embryos. Although there are theoretical risks of congenital malformations, I/We understand that the best available data from the U.S. and abroad suggests that the rate of birth defects in children born following the cryopreservation of embryos is the same as the rate observed in an age-matched group of pregnant women who conceived without assisted reproduction.

________________________________________
Patient signature                      Partner signature (if applicable)
**Disposition of Cryopreserved Embryos:** Any disposition of embryos requires the written authorization of both partners. If your embryos were formed using sperm from a third party donor, your instructions to donate these embryos must be in accordance with prior agreements with the sperm donor or applicable law. Your instructions to donate the embryos may require separate consent from the sperm donor.

I/We understand and agree that in the event of death or incapacitation of one partner, the embryo(s) will become the sole and exclusive property of the surviving partner, unless otherwise directed by law, a court order or as designated in my/our will. If the surviving partner, friends or family members wish to conceive with these embryos after your death, a legal document indicating this intent will be required.

I/We understand that IVF New England will maintain cryopreserved embryos according to the Fees for Embryo Cryopreservation and Storage policy included with this consent form. Cryopreserved embryos will be maintained until specific directives and authorization for those directives are provided by me/us. Options for disposition are discussed in the Consent for Treatment book. When I/we have decided on the method of disposition of my/our embryos, I/we 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 RSC 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 embryos if fee obligations are not met. In the event of divorce or dissolution of the relationship between patient and partner, embryos cannot be used, donated or discarded without the expressed, written consent of both parties or as directed by a court order, even if donor sperm was used.

By signing below, I / We understand and agree to the terms of the Fees for Embryo Cryopreservation and Storage policy and to the conditions stated above regarding the disposition of my/our cryopreserved embryos.

___________________________________  ______________________________________
Patient signature                                                                 Partner signature (if applicable)
ACKNOWLEDGEMENT
I/We have been fully advised of the purpose, risks and benefits of each of the procedures indicated, as well as Assisted Reproduction generally, and have been informed of the available alternatives and risks and benefits of such alternatives. This information has been supplemented by my/our consultation with my/our medical team. I/We have had the opportunity to ask questions and all my/our questions have been answered to my/our satisfaction.

I/We have read the Consent for Treatment book in its entirety and have had ample time to reach my/our decision, free from pressure and coercion, and agree to proceed with my/our participation in Assisted Reproduction services as stated.

FINANCIAL RESPONSIBILITY
Financial responsibility for all services and medical treatments provided by IVFNE, and the physicians and staff, laboratory services and hospital costs associated with medical care, are the sole responsibility of the couple receiving these treatments. IVFNE clinical and financial staff will attempt to predict, as best they can, the cost of services before they are rendered, but the costs may vary depending on unforeseen circumstances, insurance company decisions, and/or complications of the treatment. IVF New England reserves the right to change its charges and fees. IVFNE financial staff will work with the couple to determine possible insurance reimbursement for care rendered, but the ultimate responsibility for payment rests with the couple, not their insurance company.

I/We have read the IVFNE Consent for Treatment book and reviewed the information in this consent for in vitro fertilization, intracytoplasmic sperm injection, assisted hatching and embryo cryopreservation and disposition. I/We have been provided with adequate opportunity by my physician and nursing team to address our questions about the treatment elements described in this consent.

_________________________________                     __________________________________
Patient signature                                                                 Partner signature (if applicable)
Date: ________/_______/_____________             Date: ________/_______/_____________
Month       Day          Year               Month       Day          Year
Patient - Type of Picture Identification

Driver’s License # ____________     Expiration Date: _____/_____/__________
Passport #: ____________________     Expiration Date: _____/_____/__________
Other: ___________________________     Date: _____/_____/__________
Picture Identification(s) Confirmed on Date: _________/_____/______________

Witness - Print Name and Title ____________________ Witness – Signature ____________________

Partner (if applicable) - Type of Picture Identification

Driver’s License # ____________________     Expiration Date: _____/_____/_______
Passport #: ___________________________     Expiration Date: _____/_____/_______
Other: _______________________________     Date: _____/_____/__________
Picture Identification(s) Confirmed on Date: _________/_____/______________

Witness - Print Name and Title ____________________ Witness – Signature ____________________

PHYSICIAN ATTESTATION

The above mentioned patient and partner (if applicable) have been informed and counseled by me and others regarding the risks and benefits of the relevant treatment options, including non-treatment. The patient and partner (if applicable) expressed understanding of the information presented during the discussion.

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: ________________