40652

WOMEN & INFANTS HOSPITAL
Providence, RI 02905

CONSENT FOR PRE-IMPLANTATION GENETIC DIAGNOSIS (PGD)

FOR INPATIENTS: AFFIX PATIENT LABEL **OR** WRITE IN BOTH PATIENT NAME & MR NUMBER

FOR OUTPATIENTS: WRITE IN BOTH PT NAME & DOB

PATIENT NAME: _____

DOB OR MR #: _____

I _____ and _____ consent for the
(print Patient's full name) (print Partner's full name, if applicable)

performance of Preimplantation Genetic Diagnosis (PGD) testing on my/our embryo(s), which is indicated for the diagnosis of _____ by the embryology staff at Women & Infants Fertility Center (WIFC), their assignees and/or designees.

The purpose of PGD is to identify a potential pregnancy that would be affected by the genetic disorder of concern in order to guide my/our decision-making about embryo transfer.

PGD is a procedure whereby several cells are removed (biopsied) from embryo(s) (eggs fertilized with sperm) and sent to an accredited cytogenetics laboratory where they are analyzed for a specific genetic defect. The embryos are cryopreserved (frozen) and temporarily stored at WIFC while the results of the genetic analysis are pending. This may result in the freezing and storage of embryos that subsequently are identified to have an abnormal or undesired genetic diagnosis and are not used to attempt a pregnancy.

I/we understand that embryo biopsy and PGD testing are relatively new procedures with unknown risks. The known risks and benefits of this process have been explained to me/us and I/we understand them. These risks include but are not limited to:

- Damage or destruction of the embryo during the biopsy, freezing or thawing period. Should this happen, I/we may be unable to achieve a pregnancy during this IVF cycle.
- Misdiagnosis - no guarantee has been given to me/us regarding the outcome of this test

I/we understand that the lists of risk and complications related to these procedures are not complete and that my/our physician has discussed with me/us that other unforeseen risks do exist and that additional procedures may be required. I/we consent to those procedures which my/our physician deems necessary.

I/we acknowledge that due to either an inadequate number of sperm or eggs, and/or poor fertilization or embryo development, embryo biopsy may not be possible. I/we understand the blastocysts are extremely fragile and it may be impossible to perform PGD on them. In that case, I/we understand that I/we may not have genetic test results to guide our decision-making about embryo transfer.

WIFC makes the clinical recommendation to proceed with PGD if a specific single gene disorder is suggested by my/our clinical history. I/we understand that PGD only tests for the specific genetic disorder that we are concerned about and does not test for or diagnose any other specific genetic disorders.

I/we understand that PGD does not test for whole chromosome disorders (*e.g.* Down Syndrome). I/we understand that these disorders can simultaneously be screened for by another test called Preimplantation Genetic Screening (PGS). If I/we choose to use PGS, I/we understand that I/we will need to sign a separate consent form.

I/we understand that some diseases or disorders require an embryo to have two alterations (one from each parent) to be affected. Embryos with only one alteration are not likely to be affected by the disease or disorder and can be transferred in attempt to achieve pregnancy. Embryos that are affected by disease

or disorder are discarded after the diagnosis is made.

Before PGD, I/we understand that I/we have the option to meet with a genetic counselor to review my/our family history, to receive information about procedures and tests available to me/us based on my/our genetic risks, and to give me/us an opportunity to have my/our questions answered. Genetic counselors are available through the prenatal diagnostic center at Women and Infants Hospital.

I/we understand that preimplantation genetic analysis is limited by the technology and the number of cells examined. Because of this limitation, if pregnancy is achieved, I/we understand that I/we should consider routine prenatal diagnosis through chorionic villus sampling (CVS) or amniocentesis to confirm that there are no detectable genetic or chromosomal abnormalities present within the fetus.

I/we understand that congenital abnormalities, birth defects, cognitive deficiencies and other possible deviations from normal can occur following natural conception or conventional in vitro fertilization, and they may also happen following the transfer of embryos that have undergone PGD.

I/we understand that if pregnancy is successfully established, miscarriage, ectopic pregnancy, stillbirth and other abnormalities can still happen.

I/we understand that insurance coverage for any or all of these procedures may not be available and that I/we we will be personally responsible for the expenses of this treatment. The expenses may consist of hospital charges, laboratory charges, and/or physician professional fees.

I/we understand and acknowledge that both Women & Infants Fertility Center and the Women & Infants Hospital are required, under the Fertility Clinic Success Rate and Certification Act of 1992, to submit information about our PGD procedure to the Centers for Disease Control (CDC). Furthermore, data collected by the Society of Assisted Reproductive Technologies (SART) is used to generate statistics published annually in medical and scientific publications and for selected research projects. For such activities, my/our data is de-identified (information that could potentially lead to identifying the subject is removed). I/we understand that all information about me/us obtained by the program will be handled confidentially and that neither my/our identities nor specific medical details will be revealed without my/our consent. Specific medical details may be revealed in professional publications as long as my/our identities are concealed.

I/we understand that I/we can chose not to continue with PGD at any time during the process and that this decision will not affect any present or future medical care and treatment from Women and Infants Fertility Center.

I/we acknowledge that this form has been explained to me/us and I/we understand its contents. I/we have also had the opportunity to review the separate preimplantation genetic diagnosis consent form from the genetics laboratory where the PDG analysis takes place, and I/we understand its contents. I/we have had the opportunity to ask questions which have been answered to my/our satisfaction.

Time: _____ A.M./P.M. Date: _____ Signature: _____
Patient

Time: _____ A.M./P.M. Date: _____ Signature: _____
Partner, if applicable

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WRITE IN BOTH PATIENT NAME & MR NUMBER

FOR OUTPATIENTS: WRITE IN BOTH PT NAME & DOB

PATIENT NAME: _____

DOB OR MR #: _____

Provider's Acknowledgement:

I confirm that consent, as described above, has been given by this patient (and partner, if applicable)

Time: _____ A.M./P.M. Date: _____ Signature: _____
(Provider)

Print Name:_____
(Provider)

Interpreter's Acknowledgement (if applicable):

I confirm that consent as described above, has been given by this patient (and partner, if applicable)

Time: _____ A.M./P.M. Date: _____ Signature: _____
(Interpreter)

Print Name:_____
(Interpreter)