WAKE FOREST
UNIVERSITY
HEALTH SCIENCES

CONSENT FORM FOR SINGLE-GENE PREIMPLANTATION DIAGNOSIS

We (Patient name) _____ and

(Partner's name)_____

of (Home address) _____

_____

have requested that the Wake Forest University Health Sciences (WFUHS) Clinical Molecular Genetics Laboratory perform Preimplantation Genetic Diagnosis (PGD) for the disease of _____the for the alterations(s) _____ .

We received PGD informed consent counseling from (Name) _____
at (Institution or Center) _____on (Date) _____ .
The patient information and consent forms regarding In vitro Fertilization (IVF) and Intracytoplasmic Sperm Injection (ICSI) have previously been or will be reviewed and signed prior to PGD testing. We have read the general information for single-gene PGD and we understand that the methods include:

a) Removal (biopsy) of 1 or 2 cells from suitable embryos three days after insemination by ICSI
b) The biopsied cells will be tested for the genetic disease for which our children are at risk
c) The diagnosis may show that all the embryos are affected
d) In the unlikely event that single-gene PGD testing fails to yield any results, we have the choice of whether or not to transfer embryos that may or may not be affected with disease
e) In circumstances of recessive disease or disorders which require inheritance of two alterations, embryos that are determined to have a single alteration will most likely be unaffected and may be transferred

After the embryo transfer, we wish that those embryos that have been determined to be affected with disease, and therefore not frozen for future transfer, be sent to the WFUHS Clinical Molecular Genetics Laboratory to confirm affected status. These embryos will be discarded after confirmational testing.

We are aware that single-gene PGD testing has an estimated 5% risk of misdiagnosis; therefore, no guarantee has been given to us regarding the outcome of this test.

We have been strongly advised to have prenatal diagnosis testing to confirm the single-gene PGD test results, and we understand the risk associated with not having prenatal diagnosis testing. We also understand the risks involved with chorionic villus sample (CVS) and amniocentesis. If we elect to have prenatal testing performed, we agree to have the sample tested at the WFUHS Clinical Molecular Genetics Laboratory.

We have been informed that some studies report that congenital abnormalities, birth defects, genetic abnormalities, mental retardation, and/or other possible differences may occur in children born following IVF, cell biopsy, and PGD testing. We understand that these problems also occur in 3-5% of children resulting from natural conception without PGD testing.

We are aware that additional genetic alterations associated with our specific disease but not identified in us might exist in an embryo and will not be examined.

We have been informed of the possible risks and consequences associated with PGD testing.

We have had the opportunity to ask questions and discuss the procedure and we have received satisfactory answers.

We consent to these procedures.

Patient Signature _____ Date _____

Partner Signature _____ Date _____

Witness Signature_____ Date _____