WAKE FOREST UNIVERSITY
HEALTH SCIENCES

**CONSENT FORM FOR FISH PREIMPLANTATION GENETIC DIAGNOSIS**

We (Patient name) _____ and

(Partner's name)_____

of (Home address) _____

_____

have requested that the Wake Forest University Health Sciences (WFUHS) Clinical Molecular Cytogenetics Laboratory perform fluorescence in situ hybridization (FISH) Preimplantation Genetic Diagnosis (PGD) to screen for (check one only) _____ aneuploidy of chromosomes 13, 15, 16, 17, 18, 21, 22, X, and Y **-OR-** _____ your specific chromosome rearrangement only **-OR-** _____ your specific chromosome rearrangement **AND** aneuploidy of chromosomes 13, 18, 21, X, and Y.

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 FISH PGD, and we understand that the methods include:

a) Removal (biopsy) of 1 or 2 cells from suitable embryos three days after IVF
b) The biopsied cells will be tested for aneuploidy of only the chromosomes listed above
c) The diagnosis may show that all the embryos are abnormal
d) In the unlikely event that FISH PGD testing fails to yield any results or partial results, we have the choice of whether or not to transfer embryos that may or may not have abnormal chromosomes
e) In circumstances of a mosaic embryo, which is a mixture of normal and abnormal cells, a false negative (the test indicates a normal embryo, but in reality the embryo is abnormal) test result may occur and therefore an abnormal embryo may be transferred

We have been informed that each person in the general population has a 1/230 risk for carrying a balanced chromosome rearrangement. We have each been offered the option of chromosome analysis in order to determine if either of us has a chromosome difference.

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

We are aware that FISH PGD testing has an estimated 10-15% risk of misdiagnosis, therefore, no guarantee has been given to us regarding the outcome of this test.

We have been advised to have prenatal diagnosis testing to confirm the 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 Cytogenetics 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 any additional unidentified genetic alterations that may exist in us might be transferred to 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 _____