Consent Form

Preimplantation Genetic Diagnosis (PGD)

We have previously signed the consent form for In Vitro Fertilization (IVF), and we now have decided to consent to proceed with Preimplantation Genetic Diagnosis (PGD). Individuals who have experienced recurrent miscarriage, have undergone failed IVF attempts, or are in the advanced maternal age group may experience low pregnancy rates. The low pregnancy rates may be due to abnormalities in the number of chromosomes present in the embryos. An imbalance in the number of chromosomes generally leads to arrested development of the embryo. In rare cases, the pregnancies may progress and live births may result, such as seen with Trisomy-21 (Down Syndrome). In addition, couples may be carriers of single gene defects that they want to avoid passing on to their children. Cytogenetics laboratories are able to screen for abnormalities in the chromosomes and single gene defects. The goal is to screen embryos for common abnormalities in chromosome number or specific genes prior to embryo transfer. Preimplantation screening may allow the transfer of embryos which have a higher rate of implantation, higher pregnancy rate and ultimately a higher birth rate.

PROCEDURES:

Before undergoing Preimplantation Genetic Diagnosis (PGD), you will meet with a genetic counselor to review your family history, to receive information about procedures and tests available to you based on your genetic risks, and to give you an opportunity to have your questions answered. Genetic counselors are available through the Prenatal Diagnosis Program at OHSU.

The actual procedure of Preimplantation Genetic Diagnosis (PGD) consists of the following steps: Following fertilization, the embryos will be allowed to grow in culture until they reach the 6-10 cell stage on day-3 post-insemination. The procedure of Preimplantation Genetic Diagnosis (PGD) begins with the biopsy of one or two cells on these day-3 embryos. The biopsies will be sent to an accredited cytogenetics laboratory. Following biopsy, the embryos will be kept in culture until they reach the blastocyst stage on day-5 or 6. The biopsied cells will be analyzed for the correct number of all chromosomes, or DNA analysis for a specific gene defect. After analysis, the results will be discussed with you and a decision will be made on the embryos for transfer. Any remaining unaffected embryos can be frozen and stored if desired. Affected embryos will be either discarded or donated for further chromosomal studies if you consent. Donated embryos will be identified by an arbitrary number to preserve their anonymity.

RISKS AND DISCOMFORTS:

Preimplantation diagnosis only screens for some of the common chromosomal abnormalities or specific genes. Not all chromosomal abnormalities or gene defects can be detected and there is still a risk of delivering a baby with a chromosomal or gene disorders. Also, in 1-5% of cases, the results of Preimplantation Genetic Diagnosis (PGD) may be inconclusive. In other words, the test failed to pick up an abnormality that exists or no signal was visible.

Because preimplantation genetic analysis is limited by the technology and the number of cells examined, it is recommended that any patient who conceives after this technique 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. CVS or amniocentesis would be offered to you based on your age or genetic risk alone. The refusal to undergo CVS or amniocentesis may leave you in the same position as if you had conceived a child naturally, with the same risks of producing a child who has genetic or chromosomal abnormalities. Congenital abnormalities, birth defects, genetic abnormalities, mental retardation and other possible deviations from normal can occur following natural conception, conventional In Vitro Fertilization (IVF), and may also occur following the transfer of embryos that have undergone PGD. Damage or destruction of the embryo is also a potential risk of PGD, although this risk is small.

We have reviewed the costs of treatment and will be personally responsible for all expenses. The expenses include, but are not limited to, hospital charges, laboratory charges, and physician professional fees.

All of our questions have been answered, and we know that any future questions concerning our care will be answered by our physician.

We have been assured that all information about us obtained during these procedures will be handled confidentially and that neither our identity nor specific medical details will be revealed by clinic personnel without our consent.

We wish to have any remaining unaffected embryos stored by freezing? ❒ **Yes** ❒ **No**

We wish to donate any affected embryos for further chromosomal studies? ❒ **Yes** ❒ **No**

We wish to discard any affected embryos? ❒ **Yes** ❒ **No**

_____	_____	_____
Signature of Female Partner	Date	Signature of Spouse/Partner
_____		_____
PRINTED name of Female Partner		**PRINTED** name of Spouse/Partner
_____		_____
Signature of Physician		Signature of Witness (Other than Physician)

Note: This consent form must be signed by patient and partner in the witness of an Oregon Health & Science University employee or physician.