



## **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). It is known that older women undergoing In Vitro Fertilization (IVF) have low pregnancy rates. In part, 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). Special laboratories are now able to screen for abnormalities in some of the chromosomes and single gene defects. Unfortunately, not all chromosomes nor single gene defects can be easily screened at this time. Nevertheless, 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 counseling may be scheduled through the Oregon Health & Science University Prenatal Diagnosis Program by calling (503) 494-7577.

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. 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 subjected to chromosomal (for chromosomes 13, 15, 16, 17, 18, 21, 22 X and Y) or DNA analysis. 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 stored frozen 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 this technique will not detect specific gene defects, there is the chance that offspring may be born with genetic disorders.

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 Preimplantation Genetic Diagnosis (PGD). Death of the embryo is a potential risk of Preimplantation Genetic Diagnosis (PGD).

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.**