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PREIMPLANTATION GENETIC SCREENING (PGS) OR DIAGNOSIS (PGD)

Information and Consent

Introduction/Purpose:

Your physician has recommended that you undergo preimplantation genetic screening or diagnosis (PGS/PGD). PGS/PGD is carried out in four steps: 1) in vitro fertilization with intracytoplasmic sperm injection (IVF/ICSI); 2) the removal (biopsy) of cells from normally developing embryos; 3) cryopreserving biopsied embryos 4) analysis of these cells to detect abnormal gene(s) and/or chromosomes; 5) transfer to the uterus of the embryo(s) that were tested normal. The purpose of this technique is to decrease the chance of having a child that is affected by a particular genetic disorder, to decrease the change of a miscarriage, or to improve your chance of becoming pregnant after previous failed IVF attempts. PGD is ordinarily used to test embryos for specific single gene mutations, while PGS is used to verify that the number of chromosomes in an embryo is correct.

Procedures:

In Vitro Fertilization:

IVF/ICSI has resulted in the birth of many thousands of babies in the United States to infertile couples. While you may not be infertile, the same medical techniques and procedures will be used in obtaining your eggs and fertilizing them outside your body. IVF itself is a routine practice throughout the world. However, there are risks associated with IVF such as multiple gestation, ectopic pregnancy, miscarriage and ovarian hyperstimulation. When ovarian stimulation is complete, your eggs will be retrieved under transvaginal ultrasound guidance. Only mature eggs are inseminated with sperm. Once fertilization takes place, embryos are formed. The IVF Consent form which you have read and signed cover the IVF process in detail.

Embryo Biopsy and Genetic Assessment:

Normally developing blastocysts will undergo biopsy. After this step the embryos will either be returned to culture or frozen to allow subsequent genetic analysis of the biopsied cell(s). One or more embryos that do not appear to have the disease or abnormal chromosome number will then be transferred into the uterine cavity. Embryos that have a high likelihood of a genetic disorder or an abnormal number of chromosomes will not be transferred. If an embryo has undergone testing but the results are inconclusive, it should be considered at high risk for being abnormal.

Certain genetic tests are performed at facilities outside of Northwestern. Separate consent processes between you and the testing facility must be completed before the treatment can be initiated. There may be additional risks associated with transporting the biopsies and obtaining the test results in a timely way.

If you choose to donate your embryos at the risk of genetic disorders for research or quality assurance purposes, they will not be permitted to undergo further development, will not be stored for future clinical use, and will not be given to another patient.

Additional Testing:

If your embryos are being tested for a specific disease, and you have more than two embryos available for transfer, the cells may also be tested, using PGS, for some common chromosomal abnormalities such as Downs or Turner Syndrome which results from an abnormal number of chromosomes. By testing for chromosomal abnormalities, your risk of miscarriage is reduced.

In addition, the embryos may need to undergo additional testing if the biopsy failed to provide the needed results. Prior to undergoing a re-biopsy, you will be informed. You will also be informed of any additional risks and costs that may be incurred.

Risks:

PGS/PGD requires the removal of cells from the embryo (embryo biopsy), which may result in the embryo being lost or damaged. If the embryos to be tested are already cryopreserved, they must be warmed to allow for embryo biopsy and testing. There is a risk that embryos may be damaged or lost during the cryopreservation and warming processes.

Damaged embryos should be considered not suitable for transfer. Numerous animal studies and human studies have shown that embryo biopsy should not affect the development of the baby. This embryo biopsy procedure has been performed on human embryos at centers in the United States and around the world since 1989. However, we are uncertain of all the potential long-term risks that could occur as a result of micromanipulation. The effect of combining IVF, cryopreservation, microsurgical biopsy and embryo transfer on normal fetal development is also unknown.

The genetic test may fail to correctly diagnose the embryo as being genetically normal or having a disorder. If you are undergoing PGD to detect a specific hereditary disorder, or if you are 35 years old or older at the time of your pregnancy, we strongly recommend a chorionic villus samples (CVS) or an amniocentesis be performed for chromosomal analysis and testing for the specific disease. If any abnormality of the fetus is identified or risks of other genetic disorders be recognized, these findings will be discussed with you in detail.

Some embryos may be categorized as mosaic, which means the embryo has a mixture of normal and abnormal cells. If this occurs, you will have an additional conversation with your physician about embryo disposition.

Costs:

The cost of PGS/PGD may not be covered by your insurance policy. You will be responsible for any costs associated with this testing.

We have read this form and the procedure for PGS/PGD has been explained to us. We have been given the opportunity to ask questions and our questions have been answered to our satisfaction. If we have additional questions, we have been told who to contact. We agree to proceed with the in vitro fertilization process using PGS/PGD as described above and will receive a copy of this consent form after we sign it.

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CONSENT FORM

Please indicate your choices for the following situation and initial your choice to confirm you decision:

		Patient Initials	Partner Initials
1.	Testing embryo(s) for chromosome number:		
	☐ Yes – perform chromosome number testing	_____	_____
	☐ No – DO NOT perform chromosome number testing	_____	_____
2.	Number of cryopreserved embryos to be thawed for biopsy and testing:		
	☐ All cryopreserved embryos at FRM	_____	_____
	☐ Specify the number to be thawed and biopsied for testing	_____	_____
3.	Number of embryos for biopsy and testing:		
	☐ All normally developing embryos	_____	_____
	☐ Biopsy and test only if the number of normally developing embryos is > (___)	_____	_____
4.	Embryos that will not be transferred because of the risk of genetic disorders* will be:		
	☐ Allowed to be thawed and discarded	_____	_____
	☐ Allowed to be used for research or quality assurance purposes and discarded	_____	_____
	☐ Shipped to a third party long-term storage facility *(I/We are responsible for the costs of shipping and storage charge by the long-term storage facility)*	_____	_____

*Disposition of embryos with inconclusive results (including mosaicism or no amplification) will be discussed with you by your physician.

I/We have read the Preimplantation Genetic Screening (PGS) or Diagnosis (PGD) Information Guide and the procedure for PGS/PGD has been thoroughly explained to me/us. I/We have been given the opportunity to ask questions and they have been answered to my/our satisfaction. I/We have agreed to proceed with the In-Vitro Fertilization process using PGS/PGD as discussed.

Patient Name – please PRINT	Date of Birth	Patient Signature	Date

Partner Name (if applicable) – please PRINT	Date of Birth	Partner Signature	Date