

CONSENT TO EMBRYO BIOPSY FOR THE PURPOSE OF PREIMPLANTATION GENETIC DIAGNOSIS

North Hudson IVF Center requests your consent to participate in a procedure for *embryo biopsy* for the purpose of preimplantation genetic diagnosis (PGD) in your IVF procedure. PGD is a relatively new procedure in which eggs or embryos are tested for certain genetic conditions prior to being replaced in the womb. Note that there are extra costs associated with this procedure.

The whole procedure consists of five different steps, usually performed by different people and laboratories:

1. In Vitro Fertilization (IVF) by which embryos are produced.
2. Embryo biopsy, by which one cell of the embryo is removed to be analyzed
3. Analysis of the biopsied cell(s) by fluorescent in situ hybridization (FISH)
4. Embryo transfer, whereby the embryos to the female patient, is done by the physicians at North Hudson IVF Center. This consent form covers the second and third procedures, the embryo biopsy and genetic analysis. You will also be presented with other consent forms such as one for aneuploidy or genetic testing as well as another one for IVF and embryo transfer.

The preferred method for Embryo Biopsy is to remove one cell with a micropipette from the embryo on Day 3 of development; at this stage a normally developing embryo usually has 6 to 10 identical cells, each with a full complement of chromosomal material. The embryo(s) remain in incubation while the biopsied cell is tested.

Embryo biopsy consists of making a small opening in the zona (the coating of the embryo) and the cell is removed with a micropipette. The process requires temporary removal of calcium and magnesium from the culture medium that aids in the removal of the cell, and helping to avoid embryo damage. Normally only a single cell is removed from each embryo. This cell is expected to be identical to all the other cells, but it may be necessary to remove a second cell according to circumstances.

North Hudson IVF Center, at present, is uncertain of the risks involved in microsurgery (embryo biopsy) of the embryos, but believe them to be acceptably low. Numerous animal studies and some human studies show that the microsurgery of the embryo needed to remove the cells does not affect the normal development of the baby. This procedure, however, has been performed in a limited number of studies on human embryos, so the precise negative effects if any, are unknown. In animal studies there have been no apparent problems and preliminary evidence with human eggs and embryos suggests that this is also true. Even though there have been more than 1,000 live births after Embryo Biopsy/PGD world wide to date, this procedure is still relatively new; and therefore the major risk is that the procedure will not be successful in spite of all best efforts. Although a rare occurrence (less than 1%), it is possible that embryo(s) may be accidentally damaged during biopsy and cease development. The procedure may delay cell division for a few hours after which the embryo(s) will continue its development. Finally, Embryo Biopsy may fail in any individual case because of unforeseen technical malfunctions; this can include, but is not inclusive of loss of any individual cell during shipment to the testing laboratory. It is, therefore, not possible to guarantee pregnancy after Embryo Biopsy/PGD or even to promise that there will be benefits for any individual case.

Your decision whether or not to have Embryo Biopsy will not prejudice your future relations with North Hudson IVF Center and the treatment you are now undergoing. If you decide to participate, you are free to discontinue participation at any time. Your participation is voluntary and your refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled.

PRE-IMPLANTATION GENETIC DIAGNOSIS (PGD) FOR ANEUPLOIDY SCREENING:

1. The purpose of PGD for aneuploidy screening is to attempt to determine which embryo(s) have certain common numerical abnormalities of chromosomes (aneuploidy) and are therefore not suitable for implantation.

2. The screening is performed on 1 (sometimes 2) cells that an embryologist at the reproductive center has removed from each developing embryo and has sent to the laboratory.
3. The expected benefits are higher rates of implantation, lower rates of miscarriage, and possibly higher rates of live-born babies.
4. The limitations of this screening are:
 - a It cannot detect numerical abnormalities of all the chromosomes.
 - b It cannot detect structural abnormalities of any chromosome.
 - c It cannot detect mosaicism, which is the presence of chromosome abnormalities in some cells of the embryo but not in other cells of the same embryo.
 - e For aneuploidy screening the accuracy rate is 90%; therefore the error rate is 10%.
 - f Neither familial chromosome rearrangements nor single gene disorders can be determined with this test (other tests may be available for these in certain situations — ask your doctor).
 - i It is possible that none of the cells from your embryos will be found to be normal.

PRE-IMPLANTATION GENETIC DIAGNOSIS (PGD) FOR FAMILIAL TRANSLOCATIONS:

1. The purpose of PGD for familial translocations is to attempt to determine which embryo(s) have an unbalanced chromosome complement inherited from the parent known to carry a balanced translocation. Such embryos would not be suitable for implantation.
2. The testing is performed on 1 (sometimes 2) cells that an embryologist at the reproductive center has removed from each developing embryo and has sent to the laboratory.
3. The expected benefits are higher rates of implantation, lower rates of miscarriage, and possibly higher rates of live-born babies.
4. The limitations of this testing are:
 - a. It cannot detect any abnormalities of chromosomes other than the one(s) known to be involved in the parental translocation.
 - c. It cannot detect single gene disorders.
 - d. For translocation PGD the accuracy rate has not been established.
 - e. It is possible that none of the cells from your embryos will be found to be normal.

ADDITIONAL INFORMATION APPLICABLE TO PGD PERFORMED FOR BOTH PURPOSES:

1. The risk of PGD is that the limitations described above could lead to normal test results when in fact a chromosome abnormality with subsequent serious health consequences is present in the embryo. For this reason, standard prenatal diagnosis by chorionic villi sampling or amniocentesis is strongly recommended.
2. No test(s) will be performed on the cells from your embryos other than those authorized by your doctor. In PGD all material in the original samples is used in the testing process; there is no material to discard afterwards.
3. The laboratory will disclose the results of the PGD ONLY to your doctor or to his/her agent, unless otherwise authorized by you or required by law.
4. The decision to have PGD is completely yours.
5. Your doctor may release your pregnancy outcome results to Genzyme Genetics to be used for statistical analysis of the laboratory's performance.

Fees for Embryo Biopsy and Preimplantation Genetic Analysis are in addition to the cost of the IVF cycle over and above those related to your normal IVF and/or egg donation procedure.

My signature below indicates that I have read, or had read to me, the above information and that I understand it. I have had the opportunity to discuss it, including the purpose and possible risk, with my doctor or someone my doctor has designated. I have all the information I need, and all my questions have been answered.

I REQUEST that North Hudson IVF Center send cells from my embryos for the PGD test(s) marked on the test requisition form. I understand and accept the consequences of this decision.

Wife's Name: _____

Signature: _____

Date Signed: _____

Husband's Name: _____

Signature: _____

Date Signed: _____

Witnessed by: _____

Signature: _____

Date Signed: _____