

Embryo Biopsy Informed Consent
For use in pre-implantation Genetic testing
Strong Fertility Center

Definitions:

Preimplantation Genetic Screening (PGS) and **Preimplantation Genetic Diagnosis (PGD)** are specialized laboratory tests that can identify embryos that have an increased chance for miscarriage or specific types of genetic defects. These tests can identify a genetic problem before an embryo is transferred to the uterus. Examples of chromosomal problems are a disease-causing gene sequence, abnormal chromosome copy number (aneuploidy), structural abnormalities of a chromosome or X-linked disorders. **Embryo biopsy** is process by which cells are removed from the embryo so they can be sent for testing.

Description:

Embryo biopsy can be performed on embryos that result from IVF or donor egg cycles. If the biopsy is performed at the 6-8 cell cleavage stage, then 1-2 cells (blastomeres) are removed from each embryo. If the biopsy is performed at the blastocyst stage (5-6 days after retrieval), 5-10 trophoctoderm (placental) cells are removed. Embryo biopsy is performed at Strong Fertility Center. The cells obtained from each embryo are shipped to an outside lab for genetic testing. Only the embryos that lack the specific abnormality of interest or genetic disease are suitable for transfer into the uterus. Transfer may take place 5-6 days after retrieval for a cleavage stage biopsy. Embryos biopsied at the blastocyst stage will need to be frozen as the test results can take up to one week. When the genetic testing has been completed, the laboratory will notify you and our office. After embryo transfer you will follow routine treatment for an IVF or donor egg patient.

Benefits:

Patients who have an increased risk for miscarriage or conceiving a child with a genetic disorder can benefit from preimplantation genetic testing. For patients with a specific gene defect or chromosomal translocation, PGD will be used to test for the specific genetic area of concern. Sex determination can be performed for patients at risk of X-Linked disorders or genetic disease that affect a specific gender disproportionately. Embryos that carry a disease causing genetic abnormality or that demonstrate an unbalanced translocation will not be transferred.

Patients at risk for aneuploidy or recurrent miscarriage can benefit from PGS. Embryos that display an abnormal number of chromosomes will not be transferred as they would likely lead to a miscarriage, birth defects or a failed cycle. Identification of normal embryos has been shown to lead to a higher pregnancy rate and a lower miscarriage rate in several studies.

As part of the screening process, any patient at increased risk of heritable genetic disease should confer with a genetic counselor to discuss your particular risks. You will also learn how preimplantation testing and its alternatives can impact that risk.

Risks of Embryo Biopsy/Adverse Outcomes:

Typically if an embryo is damaged by the biopsy procedure it will stop growing and not be suitable for transfer. Animal and human studies to date have not shown that embryo biopsy impedes the normal development of an embryo. Numerous healthy live births have been reported by most IVF centers both in the US and abroad. The procedure is relatively new in human application and there can be additional risks not known at the present time. Potential risks are:

Embryo biopsy may not be possible due to technical difficulties or lack of fertilization or suitable embryo development.

Embryo biopsy may result in damage to the embryo.

Possible loss or damage to cells during the process of shipping

Failure of genetic analysis to provide adequate information

Genetic testing may reveal that there are no suitable embryos for transfer

Limitations of genetic tests used

Biopsied embryos that are cryopreserved may not survive the freezing or thawing process.

Alternatives

Attempted conception with no preimplantation genetic testing

Attempted conception with donor eggs, sperm or embryos from a donor that is known not to carry a specific gene

Attempted conception with antenatal diagnosis via amniocentesis, CVS or ultrasound

Adoption

Electing not to have future pregnancy

Important Points

In addition to this consent form, you will need to read and sign an **IVF consent**, an **Embryo disposition consent** (both provided by Strong Fertility) and a **PGS and/or PGD consent** (provided by the laboratory performing your testing). Each form will address the risks and benefits of the procedure or test. The IVF and Preimplantation Genetic Testing consents address confidentiality issues pertaining to the data obtained as a result of this treatment.

No test is perfect and errors can occur. Contamination, inadequate sample size or errors in processing can lead to test results that are inconclusive/inadequate. There is a possibility of test results producing a wrong diagnosis. Current literature suggests that error rates are less than 1.0 % per embryo. The actual rates depend on the platform being used and will be stated by the laboratory on their consent form. For this reason, we strongly suggest that you consider antenatal diagnosis (amniocentesis, CVS, NIPT) if pregnancy occurs. PGD/PGS can detect a specific chromosomal problem but it does not detect all problems and it is not intended as a substitute for routine prenatal testing. Birth defects and other problems can occur in pregnancies that are chromosomally normal and would not be detected by PGD/PGS.

We use a messenger service that specializes in overnight medical transportation to ship your specimens to the testing laboratory. Strong Fertility Center cannot be responsible for any loss or damage that occurs during the shipping process or problems that occur during testing at an outside lab.

When PGD/PGS test results become available we will contact you to review your embryo transfer plans. We will also review disposition of all embryos not transferred. It is our policy to not knowingly transfer any abnormal embryos. The laboratory doing your genetic testing will provide a report of your results. At the time of your embryo transfer we will provide a summary of your embryos and their disposition. It is also possible that you may be told there are no normal embryos available and in that case no embryo transfer would be performed.

We are interested in the outcome of your pregnancy. We request permission to contact your Obstetrician for the results of your chorionic villus sampling or amniocentesis, prenatal care and delivery outcome. We may also need to contact your pediatrician for growth and development information. All of this information is collected for statistical purposes and is treated with strict confidentiality.

Your signature below acknowledges that you have read this consent form in its entirety as well as the IVF consent, embryo disposition consent and the consent for PGS/PGD provided by the outside center performing that testing. You understand the potential risks and benefits of embryo biopsy and PGS/PGD and that you have had the opportunity to ask questions. You agree that those questions were answered to your satisfaction. You have considered the alternatives and have sufficient information to base your decision.

[I/We do jointly and severally release and forever discharge the physicians and all employees of Strong Fertility Center from any and all claims, demands, costs, expenses or loss of services incurred as a result of the physical or mental nature of any child or children produced using these procedures.]

Patient Name (Please Print and Sign)

Date

Partner Name (Please Print and Sign)

Date

Physician

Date