Strong Fertility Center

Kathleen Hoeger, MD, MPH, Director
Snigdha Alur-Gupta, MD
Erin Masaba, MD
John T. Queenan Jr., MD
Wendy Vitek, MD

Embryo Biopsy Informed Consent

For use in pre-implantation Genetic testing

Strong Fertility Center

Definitions:

Pre-implantation Genetic Testing--aneuploidy (PGT-A), Pre-implantation Genetic Testing—structural rearrangements **(PGT-SR),** and **Pre-implantation Genetic Testing--monogenetic/single-gene defects (PGT-M)** 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 (5-7 days after retrieval), 5-10 trophectoderm (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 genetic testing results can several weeks to result. When the genetic testing has been completed, the outside 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 pre-implantation genetic testing. For patients with a specific gene defect or chromosomal translocation, PGT-M or PGT-SR 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 a genetic disease that affects a specific genetic sex 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 PGT-A. 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 their particular risks. They will also learn how pre-implantation 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, lack of fertilization, or lack of suitable embryo development.
- Embryo biopsy may result in damage to the embryo.
- Possible loss or damage to cells during the shipping process
- 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 pre-implantation genetic testing
- Attempted conception with donor eggs, donor 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 **PGT-A, PGT-SR, and/or PGT-M consent** (provided by the outside laboratory performing your testing). Each form will address the risks and benefits of the procedure or test. The IVF and Pre-implantation 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. PGT can detect a specific chromosomal problem, but it does not detect all problems and 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 PGT.

We use a third-party courier 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 your PGT-A/PGT-SR/PGT-M test results become available, we will contact you to schedule your follow up appointment with your physician within 7 days. At this time, we will review your embryo transfer plans and 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.

All biopsied embryos will be frozen and stored at Strong Fertility Center, regardless of genetic testing results, until they are transferred, donated, or discarded. *It is the patient's responsibility to pay for embryo storage and to inform the clinic promptly if they desire to discard any genetically abnormal embryos.*

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 PGT-A, PGT-SR, and/or PGT-M provided by the outside center performing that testing. You understand the potential risks and benefits of embryo biopsy and PGT, and 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 on which to base your decision.

By signing below, I/We do jointly and separately 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 (Print)	Date of Birth
_____	_____
Patient Signature	Date
_____	_____
Partner Name (Print)	Date of Birth
_____	_____
Partner Signature	Date
_____	_____
Physician Signature	Date