

CONSENT FORM FOR EMBRYO BIOPSY WITH PREIMPLANTATION GENETIC TESTING FOR DISEASE CAUSING GENETIC MUTATIONS or CHROMOSOMAL STRUCTURAL REARRANGEMENTS

In vitro fertilization (IVF) treatment followed by embryo biopsy provides the opportunity to perform genetic testing on the embryo before it is transferred into the uterine cavity. **Preimplantation Genetic Testing for monogenic (single gene) defects (PGT-M)** involves the testing of the embryo for genetic mutations which cause a specific disease. **Preimplantation Genetic Testing for structural rearrangements (PGT-SR)** involves the testing of the embryo for abnormal structural rearrangements of the chromosomes. Both **PGT-M** and **PGT-SR** were previously referred to as Preimplantation Genetic Diagnosis (PGD).

This consent form supplements the consent form entitled “**Consent for In Vitro Fertilization, Intracytoplasmic Sperm Injection, Assisted Hatching and Embryo Cryopreservation/Disposition.**”

DESCRIPTION

The embryo biopsy is typically performed 5-6 days after the egg retrieval when the embryo has developed to the blastocyst stage. The biopsy of the embryo is performed after making a small opening in the outer membrane that surrounds the embryo. In some cases, it may be necessary to take a second biopsy if the testing turns out to be inconclusive. The blastocyst is cryopreserved immediately after biopsy. The biopsy sample is then sent to an outside genetics laboratory for genetic testing. The embryo remains in our laboratory while the biopsied cells are being tested in the genetics laboratory. The genetic testing results are usually available 10-14 days later. Once the results are known, the genetically normal embryos can be transferred in a future thaw cycle.

The reported results of genetic testing of the embryos can be one of following:

1. **Unaffected-** these embryos do not have the genetic mutations or abnormal chromosomal rearrangements being tested for.
2. **Inconclusive-** these embryos, if viable, may be re-biopsied to determine their genetic status.
3. **Affected-** these embryos have the genetic mutations or abnormal chromosomal rearrangements being tested for.

After the test results are available you will meet with your physician to review the results and discuss future plans moving forward.

RISKS

Numerous animal studies and some human studies have demonstrated that embryo biopsy does not affect the normal development of the offspring. However, there may be unforeseen risks to the fetus/offspring as a result of this procedure.

Other potential risks of performing the embryo biopsy include:

1. The biopsy cannot be performed because the eggs do not fertilize or the embryos stop developing.
2. The biopsy rarely renders the embryos non-viable or less likely to implant.
3. Technical problems prevent the embryo biopsy from being accomplished.
4. The biopsied cells obtained are destroyed or lost during transport to the outside laboratory.
5. Genetic testing results confirm that there are no genetically unaffected embryos.
6. Embryos that are previously frozen may not survive the thawing process.
7. The genetic testing of the embryo may be inaccurate or inconclusive.



ACKNOWLEDGEMENT OF INFORM CONSENT AND AUTHORIZATION

By signing this document, we (I) acknowledge that we (I) have read this consent and we (I) have had a thorough discussion with our (my) Boston IVF physician and all of our (my) questions concerning the treatment have been fully answered to our (my) satisfaction. This discussion included information on the risks, benefits and complications of embryo biopsy with genetic testing.

Furthermore, we (I) acknowledge that the discussion with our (my) Boston IVF physician and caregivers was in a language that we (I) understand and we (I) were (was) provided sufficient information to allow us (me) to make an informed decision whether or not to proceed with this treatment.

We (I) have also considered other alternatives. We (I) are (am) also aware that there are other ways to perform genetic testing of the fetus after a spontaneous conception including chorionic villous sampling and genetic amniocentesis.

We (I) understand that Boston IVF is not responsible for any problems that result from the transport of cells to the outside laboratory or any problems that occur with the testing of the cells.

We (I) are (am) aware that no genetic testing is 100% accurate and that other testing (for example, chorionic villous sampling or amniocentesis) is strongly recommended to confirm the results of the genetic testing.



Notarization Form (This form is only needed if not able to have witnessed at Boston IVF)

Patient Name (print) **Patient Signature** / /
Today's Date (MM/DD/YYYY)

State of: _____ County of: _____

On this _____ day of _____ 20____, before me, the undersigned notary public, personally appeared

_____, proved to me through satisfactory evidence of identification, which were _____, to be the person whose name is signed on the proceeding or attached document in my presence.

ID NUMBER: _____ Expiration Date: / /
(MM/DD/YYYY)

 / /
Today's Date (MM/DD/YYYY)

Notary Signature

Title
My appointment expires: / /
(MM/DD/YYYY)

Partner Name (if applicable, print) **Partner Signature** / /
Today's Date (MM/DD/YYYY)

State of: _____ County of: _____

On this _____ day of _____ 20____, before me, the undersigned notary public, personally appeared

_____, proved to me through satisfactory evidence of identification, which were _____, to be the person whose name is signed on the proceeding or attached document in my presence.

ID NUMBER: _____ Expiration Date: / /
(MM/DD/YYYY)

 / /
Today's Date (MM/DD/YYYY)

Notary Signature

Title
My appointment expires: / / (MM/DD/YYYY)