

CONSENT FORM FOR EMBRYO BIOPSY WITH PREIMPLANTATION GENETIC TESTING FOR ANEUPLOIDY

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 Aneuploidy (PGT-A)**, previously known as Preimplantation Genetic Screening (PGS), involves the testing of the embryo for the number of chromosomes and/or to determine the sex of the embryo.

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. (There may be rare instances when the embryo biopsy is performed 3 days after the egg retrieval when the embryo has developed to the cellular 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 chromosomally normal embryos can be transferred in a future thaw cycle. In the rare instance when the biopsy is taken on day 3 embryos, the test results may be available within 48 hours in which case the embryo transfer may be performed on day 5 during the same cycle. There may also be rare instances when the biopsy is taken on day 5 and the test results may be available within 24 hours, in which case the embryo transfer may be performed on day 6 during the same cycle.

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

1. **Chromosomally normal** –these embryos are suitable for transfer into the uterine cavity to establish a pregnancy.
2. **Chromosomally abnormal**- these embryos will be discarded.
3. **Inconclusive**- these embryos will be thawed, re-biopsied (if viability confirmed) and then refrozen. Following the genetic testing, if the embryos are confirmed to be chromosomally abnormal they will be discarded.

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 embryo 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 indicate that there are no chromosomally normal embryos. For sex selection cases, there may be no embryos of the desired sex.
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, 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 preimplantation genetic screening.

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 genetic testing is not 100% accurate and that other testing (for example, chorionic villous sampling or amniocentesis) may be recommended to confirm the results of the genetic testing.

It is required that you have this document witnessed at Boston IVF, if unable because of distance the default is to have this document officially notarized.



Witness of Consent Form (if this form is completed no need to complete notarization form)

Patient Name (print)

Patient Signature

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

PATIENT- TYPE OF PICTURE IDENTIFICATION: Driver's License Passport Other: _____

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

Witness Name and Title (print)

Witness Signature

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

Partner Name (if applicable, print)

Partner Signature

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

PARTNER - TYPE OF PICTURE IDENTIFICATION: Driver's License Passport Other: _____

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

Witness Name and Title (print)

Witness Signature

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

Physician Attestation

The above mentioned patient and partner (if applicable) have been informed and counseled by me and other team members regarding the risks and benefits of the relevant treatment options, including non-treatment. The patient and partner (if applicable) expressed understanding of the information presented during the discussion.

Physician Name (print)

Physician signature

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



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)