BOSTON IVF

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)** 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 Embryo Cryopreservation/Disposition.**"

DESCRIPTION

The embryo biopsy is typically performed 5-7 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 shell 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 testing. The embryo remains stored frozen in our laboratory while the biopsied cells are being tested in the genetics laboratory. The genetic testing results are usually available 14-21 days. Once the results are known, those embryos reported as chromosomally normal can be transferred in a future thaw cycle.

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

1. **Embryos reported as Euploid or Chromosomally Normal:** these embryos are expected to have the typical chromosome numbers needed for normal growth and development and are recommended for transfer.
2. **Embryos reported as Aneuploid or Abnormal:** these embryos are expected to have an abnormal number of chromosomes, a deletion or duplication or abnormal copy number; they will not typically be transferred and are usually discarded.
3. **Inconclusive:** these embryos will be thawed, re-biopsied if possible, refrozen and re-tested.

We (I) acknowledge that we (I) have understood the disposition of chromosomally aneuploid/abnormal embryo.

*WE (I) WISH TO **DISCARD*** CHROMOSOMALLY ANEUPLOID/ABNORMAL EMBRYOS

Initials ☐ ☐

Patient Partner (if applicable)

*WE (I) WISH TO **KEEP*** CHROMOSOMALLY ANEUPLOID/ABNORMAL EMBRYOS

Initials ☐ ☐

Patient Partner (if applicable)

If you choose to keep your embryos, they will be maintained in storage, and you will incur charges for their storage until you complete a consent to alter the disposition of the stored embryos.

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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 including and not limited to:

1. The biopsy cannot be performed because the eggs do not fertilize, or the embryos stop developing.
2. The biopsy cannot be performed due to inadequate embryo development.
3. The biopsy renders the embryo non-viable or less likely to implant.
4. Technical problems prevent the embryo biopsy from being accomplished.
5. The biopsied cells obtained are destroyed or lost during transport to the outside laboratory.
6. Genetic testing results indicate that there are no chromosomally normal embryos. For sex selection cases, there may be no embryos of the desired sex.
7. Embryos that are previously frozen may not survive the thawing process.
8. The genetic testing of the embryo may be inaccurate or inconclusive.
9. The genetic testing provider may change their analytical platforms and redefine their parameters for reporting embryos as chromosomally normal and abnormal.

We (I) are (am) aware that genetic testing is not 100% accurate. After pregnancy is achieved it is recommended that you discuss with your OB/GYN about undergoing routine prenatal genetic screening that screens the fetus for chromosomal imbalances. Other testing (for example, chorionic villous sampling or amniocentesis) may be recommended to confirm the results of the genetic testing.

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.
We (I) understand and acknowledge the risks outlined above.
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.

_____ _____ _____

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

_____

Date of Birth (MM/DD/YYYY)

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

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

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

Date of Birth (MM/DD/YYYY)

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

ID NUMBER:_____ State/Country:_____ Expiration Date:_____
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)