CONSENT FORM FOR EMBRYO BIOPSY WITH PREIMPLANTATION GENETIC SCREENING

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 Screening (PGS) involves the testing of the embryo for chromosomal imbalances and/or to determine the gender.

This consent form supplements the consent forms entitled “Consent Form for In Vitro Fertilization” and “Consent Form for Embryo Freezing, & Disposition of Eggs, Sperm and Embryos”.

DESCRIPTION
The embryo biopsy can be performed 3 days after the egg retrieval when the embryo has developed to the cellular stage or 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 biopsy sample is then sent to an outside laboratory for genetic testing. The embryo remains in our laboratory while the biopsied cells are being tested. If the biopsy is taken on day 3 embryos, the test results are generally available within 24-48 hours and the embryo transfer is then performed during the cycle. If the biopsy is taken on day 5/6 embryos (blastocyst stage), the embryos are immediately frozen and the genetic testing results will be available 10-14 days later. Once the results are known then the chromosomally 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. **Chromosomally normal** – these embryos can be transferred into the uterine cavity to establish a pregnancy.
2. **Chromosomally abnormal** – these embryos will be discarded.
3. **Inconclusive** - these embryos will be thawed, rebiopsied (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 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 in no chromosomally normal embryos. For gender selection cases, there may be no embryos of the desired gender.
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 no genetic testing is 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.

____________________________               ____________________________  ____________________________
Signature of Patient                                       Signature of Partner                                        Signature of Physician

____________________________         ____________________________
Printed name           Printed name

____________________________        ____________________________
Date of Birth           Date of Birth

____________________________        ____________________________
Date           Date

____________________________               ____________________________  ____________________________
Signature of BIVF Witness or Notary              Signature of BIVF Witness or Notary

____________________________         ____________________________
Printed Name of Witness or Notary                  Printed Name of Witness or Notary

____________________________        ____________________________
ID Type                                                             ID Type

____________________________               ____________________________  ____________________________
ID Number and Exp Date                                 ID Number and Exp Date

___________________________(State)
On this ____day of _________________, 201___,
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.

Notary Public

______________________________________

___________________________(State)
On this ____day of _________________, 201___,
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.

Notary Public