NHFC
4 Columbus Circle, 4th Fl.
New York, NY 10019
T: 212.517.7676
F: 212.489.6294

CONSENT FOR PREIMPLANTATION GENETIC SCREENING (PGS) BIOPSY

PURPOSE

The purpose of this procedure is to increase the chances of transferring into the uterus embryos that do not have recognizable chromosomal abnormalities.

BACKGROUND

Chromosomes are structures found in the center (nucleus) of cells. A human typically has 46 chromosomes, in 23 pairs. An embryo receives 23 chromosomes from the sperm and 23 from the egg. Chromosomes are made of DNA, a molecule that contains the information (genes) that instructs the body's cells how to function. Having extra or missing chromosome(s) (a situation known as aneuploidy) can result in infertility, Down syndrome, failure of an embryo to implant, and pregnancy loss.

PGS is offered to patients undergoing in-vitro fertilization (IVF) who are 35 years old or older. Patients in this age group are at increased risk of miscarriage or birth defects. PGS may reduce these risks. PGS of embryos for aneuploidy may also help the embryologists to select the embryos most likely to produce a pregnancy.

PGS of embryos for aneuploidy may also be used for patients of all ages who have unexplained failure to conceive despite several IVF cycles. The procedure may also benefit patients with a history of miscarriages, especially when testing reveals no clear explanation. Patients who have had an aneuploid pregnancy in the past may also want to consider PGS for embryos of aneuploidy.

PROCEDURE

The entire procedure consists of five different steps, usually performed by different experts and laboratories: the first part is producing embryos by In Vitro Fertilization (IVF), this part will take place at New Hope Fertility Center. The second part is preparing the embryo on day 3 for biopsy by performing assisted hatching. The third part is embryo biopsy in order to remove and analyze a small clump of cells from the blastocyst, this is done by New Hope Fertility Center. The fourth part involves wash and transfer of the cells into a small test tube, the clump of cells and embryo are frozen separately. When biopsy samples are sent out for testing at the reference laboratory, embryo remains cryopreserved at New Hope Fertility Center. The fifth step is the analysis of the cells which is performed by an outside reference laboratory.

BIOPSY AND WASHING OF CELL CLUMPS

To biopsy the cells, an embryologist from New Hope Fertility Center makes an opening in the zona using assisted hatching on the third day of embryo development in preparation for the biopsy procedure. Once the embryo advances to the blastocyst stage (between day 5-day 7), the embryologist removes between 5-7 cells via aspiration with a pipette. The embryo is frozen and the cells that were removed from the embryo are washed, transferred to a small test tube, frozen and then banked until the patient is ready to send them for analysis at an outside reference laboratory.

TRANSPORT

After receiving consent to send out for testing, New Hope Fertility Center sends the tubes containing the biopsy sample to an outside reference laboratory for analysis using same-day couriers.

ANALYSIS

The genetic material within the embryo cells (DNA) is amplified using a technique called the polymerase chain reaction (PCR). This amplification produces enough DNA to use a second technique, known as comparative genomic hybridization (CGH) or next generation sequencing (NGS). CGH or NGS assesses the amount of DNA derived from each chromosome, revealing whether or not there are a correct number of chromosomes. The cells are destroyed during this process. Therefore, they cannot be used for another purpose or returned to the embryo.

Patient Initials _____

NHFC
4 Columbus Circle, 4th Fl.
New York, NY 10019
T: 212.517.7676
F: 212.489.6294

LIMITATIONS

The reference laboratory is unable to look at the structure of the chromosomes via PGS. Because of this limitation, prenatal testing after the IVF cycle with PGS is strongly advised in order to confirm the diagnosis and review the number and structure of all the chromosomes. Prenatal testing may be performed in the first trimester of pregnancy via chorionic villous sampling (CVS) or during the second trimester via amniocentesis. CVS is a procedure carried out in the late first trimester that takes cells from the placenta and analyzes them for chromosomal abnormalities. Amniocentesis is usually carried out between 15 and 20 weeks of pregnancy- a sample of the fluid that surrounds the baby is taken, and cells from the baby that are found in the fluid are analyzed for chromosomal abnormalities. PGS should not be considered a replacement for prenatal testing, as its accuracy rate is not as high.

THE RISKS OF EMBRYO BIOPSY

PGS does not guarantee the birth of a normal baby. It is unknown whether biopsied embryos are less likely to implant than embryos that have not been biopsied. Embryo biopsy may lower implantation rates slightly in the absence of a test result, but selection of chromosomally normal embryos via PGS for aneuploidy may more than compensate for any negative effect of embryo biopsy, and it will increase the probability that the embryos transferred will implant.

If an embryo is damaged by the procedure it may stop growing and be unsuitable for transfer into the uterus. The risk of damaging an embryo during removal of the cells is less than 1%. The future fetus will be complete even if several cells are removed from the embryo at the blastocyst stage. As of December 2005, more than 2000 babies had been born from IVF with PGS, with no reported increase of congenital abnormalities above the general population rate. The rate of malformations in the general population is 3-5%. This procedure, however, has not yet been performed sufficiently to rule out any detrimental effect. Thus we strongly recommended that you have prenatal testing by chorionic villus sampling or amniocentesis.

THE RISKS OF CELL PREPARATION

After embryo biopsy, the biopsied cells are placed in a small test tube and their DNA is amplified. The cells are no longer viable in any way after this process and can only be used for PGS. Some biopsied cells may not yield a test result: some cells may contain degraded DNA, which cannot be amplified; or the clump of cells may be lost during the transfer to the test tube. Embryos without a result from the analysis may still be transferred, but the advantages of PGS may not apply.

THE RISKS OF TRANSPORT

Once the cells are placed in test tubes, a third party transports the cells to the reference laboratory for analysis using same day delivery services. Weather and air travel conditions may delay the receipt of samples. About 1/1000 cases, samples do not arrive in the reference laboratory, or even more rarely, 1/3000, samples may be damaged during transport.

THE RISKS OF THE PGS ANALYSIS

The risk of a clinical misdiagnosis resulting in a fetus or baby with chromosome abnormalities after a PGS procedure is less than 2%. This risk seems lower than that found without PGS or in natural conceptions in women of advanced maternal age. Due to the chance of misdiagnosis, as well as the presence of types of chromosome abnormality for which we do not test, we recommend prenatal testing by CVS or amniocentesis. CVS and amniocentesis offer higher accuracy and lower misdiagnosis rates than PGS.

NO NORMAL EMBRYOS- The test may find that none of the embryos are normal, and there may be no embryo transfer procedure. The likelihood that this will happen is influenced by a variety of factors, the most important of which is usually age.

NO DIAGNOSIS AND PARTIAL DIAGNOSIS - Some embryos will have no diagnosis, due to the loss of biopsied cells, or poor DNA quality (often found in damaged or dying cells). Embryos without a result can still be transferred, but all the possible advantages of PGS will not apply. In addition, sometimes the analysis may not be clear for one of the

Patient Initials _____

chromosomes being tested. This embryo could be transferred, but the possible advantages of PGS may not apply.

Because of the possibility of misdiagnosis, your pregnancy should be carefully monitored.

Between 10 to 18 weeks, we strongly recommend prenatal testing by chorionic villous sampling (CVS) or amniocentesis. The fetus should also be monitored with ultrasound examination to check its growth and development. There is no guarantee that a child will be normal after IVF with PGS.

POSSIBLE BENEFITS

In the majority of cases, aneuploid embryos are indistinguishable morphologically and developmentally from chromosomally normal ones. Thus, without genetic testing, embryologist cannot differentiate normal embryos from aneuploid embryos and you could have aneuploid embryos transferred.

Most chromosomally abnormal embryos either do not implant or spontaneously abort shortly after implantation. The probability of conceiving a healthy child may increase after PGS.

PGS for aneuploidy has been reported to double implantation rates in some studies. The test may reduce pregnancy loss and increase the chance of delivering a healthy baby.
PGS will not cause you any physical discomfort other than that experienced during a regular IVF cycle.

ALTERNATIVES

Alternatives to PGS during pregnancy include standard prenatal testing for abnormalities (chorionic villous sampling, amniocentesis, ultrasound examination). You are not obliged to undergo PGS even if your physician recommends it. The risks, benefits and alternatives of this testing should be discussed thoroughly with your genetic counselor, obstetrician or the person performing/ordering the tests. If you wish to be referred to a genetic counselor, please let us know. Although these tests may serve as alternatives to PGS, PGS is not a substitute for routine prenatal testing.

COSTS

Fees for PGS are in addition to the cost of the IVF cycle. The Finance Department of New Hope Fertility Center will advise you of the fees. If the PGS procedure is paid for but not performed, your payment will be refunded minus the cancellation fee. You are also responsible for any additional medical costs incurred as a result of complications or other medical care required as a result of receiving PGS. Insurance cover for all or any part of this total procedure may not be available, and you are personally responsible for payment of such costs, including hospital and laboratory charges, and the physician's professional fees.

CONFIDENTIALITY

Confidentiality of your records will be maintained at all times. Only personnel of the reference laboratory and New Hope Fertility Center will have access to your records. The Department of Health of your state and the Food and Drug Administration (FDA) may also inspect the records.

GENETIC CONSULTATION BEFORE PGS

It is recommended that you have a consultation with a genetic counselor that specializes in PGS before undergoing PGS. This can be arranged by the referenced laboratory.

aCGH OR NGS TESTED ABNORMAL EMBRYOS

Please note that any embryos that are deemed abnormal after aCGH or NGS testing cannot be disposed/donated for research without the proper written consent to do so. This consent requires patient and partner signature (when applicable) and to be notarized. The original consent must be returned to our office before the embryos can be either disposed/donated for research. By initialing, I understand that my abnormal embryos will not be disposed/donated for/to research without signing the embryo disposition consent form. Patient Initials _____

NHFC
4 Columbus Circle, 4th Fl.
New York, NY 10019
T: 212.517.7676
F: 212.489.6294

FOLLOW-UP

Prenatal testing during pregnancy can be carried out via chorionic villous sampling (CVS) or amniocentesis. Your obstetrician, or someone he or she refers you to, can perform these tests. If prenatal diagnostic testing is not performed, cord blood at the time of the delivery should be analyzed for chromosomes. If a pregnancy loss occurs, we request that chromosome studies be performed on the products of conception. All results from genetic testing of the pregnancy or the child up to the age of one year will be forwarded to the PGS Program Coordinator at the outside reference laboratory. This information will remain confidential and will be used to monitor outcomes of the PGS program.

We have read the entire consent form, or it has been read to us. We understand that PGS has benefits and risks, some of which may be unknown at this time. We wish to proceed with PGS for aneuploidy using CGH or NGS analysis of cells biopsied at the blastocyst stage.

We also understand that undergoing PGS for aneuploidy does not eliminate the need for standard prenatal testing such as chorionic villous sampling or amniocentesis. The need for these tests remains the same whether or not PGS for aneuploidy is performed. We understand that if we have questions about CVS or amniocentesis we may ask our obstetrician or we may request a referral to a genetic counselor. We have been given an opportunity to ask questions about the PGS procedure and the contents of this consent form. If we think of additional questions, we may contact our physician, genetic counselor or nurse.

Our signatures below indicate that we have read the above information and have had the opportunity to discuss it with our doctor, including the purpose and possible risks. We understand and accept the consequences of this decision.

_____	_____	_____
Patient Name (Print)	Patient Name (Signature)	Date
_____	_____	_____
Partner/Husband Name (Print)	Partner/Husband Name (Signature)	Date

As one of the members of NHFC, my signature indicates that the foregoing consent was read, discussed and signed in my presence.

_____	_____	_____
Witness Name (Print)	Witness Name (Signature)	Date

If this consent is not witnessed by a NHFC staff member, notarization is required for both the biopsy consent and all Reprogenetics consents.

On this _____ day of _____, 20___, the above named person(s) known to me to be the persons whose names are subscribed to within the Consent For Preimplantation Genetic Screening (PGS) of Aneuploidy Using aCGH or NGS, have personally appeared before me, a Notary Public, and acknowledge to me that she/he has read the foregoing, and that she/he knew the contents thereof, and that she/he executed the same freely and voluntarily and for the uses and purposes therein mentioned and understanding the same.

_____
NOTARY PUBLIC

STATE OF _____

COUNTY OF _____

AFFIX SEAL

Patient Initials _____

Physician Test Order – (NY13)

PGD - Preimplantation Genetic Diagnosis for Single Gene Diseases
PGS - Preimplantation Genetic Screening for Chromosome Aneuploidy

Clinical Information

Clinic Name: New Hope Fertility Center - NY13 **Today's Date:** _____

Address: 4 Columbus Circle, 4th Floor, NY, NY 10019 **Phone:** 917-790-1890

Clinic Email: daniela.hess@nhfc.com; amie.becker@nhfc.com **Clinic Contact:** Daniela Hess/Amie Becker

Physician Name: Dr. John Zhang **Signature:** _____ **M.D.**

Test Ordered

☐ **PGS – NGS / aCGH: Comprehensive Chromosome Screening for Aneuploidy**

☐ **Exclude sex from report**

***PGS Testing Programs:** ○ **8 Before 9** - (default) **or** ○ **1 by 1**

☐ **PGD: Translocation or Inversion Screening** (karyotype report required)

☐ **PGD + PGS** (analysis combined serially) ○ **PGD first** ○ **PGS first**

○ **Both tests performed simultaneously** (additional charges will apply)

☐ **PGD : Single gene inherited genetic disorder**

☐ **Batch and Hold**: PGD only (Select to batch samples over multiple PGD cycles, samples are not tested until ordered)

ICD-10 Reason for Testing (required for PGD): _____

e.g. Cystic Fibrosis; Fragile X; Chromosome Translocation; AMA; HLA; Double Disease

Anticipated Biopsy:

☐ **Day 5/6 (FET – frozen cycle)** ☐ **Day 5 (For Day 6 Fresh ET, PGS Only)** ☐ **Day 3**

Payment Options:

● **Bill Clinic** ○ **Bill Patient**

***** Genesis Genetics will perform testing as ordered on this form. If no PGS testing program is selected by, Genesis Genetics will default to the *8 Before 9* testing program. **We are required to test and invoice for all samples received.** It is the responsibility of the ordering physician to make sure that the test order is compliant with all appropriate local laws and statutes.

Patient Information

Patient: Last _____ First _____ Sex: Male ○ / Female ○

☐ **Egg Donor** Date of Birth 19 ____ ____ ____ (Year / Month / Day)

Partner: Last _____ First _____ Sex: Male ○ / Female ○

☐ **Sperm Donor** Date of Birth 19 ____ ____ ____ (Year / Month / Day)

Patient Address: _____ (Home Street Address)

_____ (City) _____ (State) _____ (Country) _____ (Postcode)

Email: _____ **Phone:** _____

Email this form to: enroll@genesisgenetics.org or Fax to: 313.544.4006

Patient Informed Consent
Preimplantation Genetic Screening (PGS) for Chromosome Aneuploidy
+/- PGD for Translocation or Inversion Testing

Patient Name: _____ _____
(Last) (Middle Initial) (First) DOB

Partner Name: _____ _____
(Last) (Middle Initial) (First) DOB

I, the undersigned, request, authorize and consent to the performance of the procedure of preimplantation genetic screening ("PGS") on samples obtained from my embryos which are submitted to Michigan Genetics, LLC (hereinafter "Genesis Genetics"). I understand that this testing is voluntary and I have had the opportunity to discuss the alternatives to this testing with my physician outside of Genesis Genetics.

I understand and agree that Genesis Genetics is acting as a reference laboratory which will perform these tests and provide the results to the ordering physician (usually at my IVF center). I understand that Genesis Genetics is not involved in the management or performance of my IVF cycle or in obtaining the samples for testing and that all medical care, including the selection of embryos for embryo transfer, is at the discretion of my physician outside of Genesis Genetics. Before testing occurs, I will read the Agreement thoroughly, ask any questions not answered by the Agreement and sign the Agreement indicating that I understand its terms.

Purpose of the Test.
Your reproductive doctor(s) has decided that the potential for a successful pregnancy may be enhanced by chromosome analysis of your eggs and/or IVF-produced embryos by performing PGS. In most cases, an embryo with an abnormal number of chromosomes does not successfully implant resulting in miscarriage. For example, there are supposed to be two chromosome 21s in each embryo cell, the presence of three usually results in miscarriage. However, if the pregnancy results in birth, the newborn will have a condition known as Down syndrome (trisomy 21). This may occur whether you become pregnant on your own or with the help of a reproductive doctor. Obtaining chromosome information about your embryos prior to transfer to the womb should improve your chances of becoming pregnant.

The purpose of this laboratory test is to attempt to identify embryos that have the correct number of chromosomes (euploid); stated differently, the test will identify large amounts of extra or missing chromosome material (aneuploidy), if present. Extra or missing chromosome material may cause an embryo to fail to implant, a pregnancy that ends in miscarriage, or a pregnancy that results in a child with significant health problems or developmental delays. The test will also identify the gender (sex) of the embryos, except for those samples that produce "No Result".

Translocation and Other Chromosomal Rearrangements. PGS technology can also be applied when an individual is known to have a specific chromosome rearrangement, such as a translocation or inversion, We call this testing preimplantation genetic diagnosis, or PGD, since we are testing embryos for an inherited genetic alteration. If you have been identified as a carrier of a chromosome rearrangement, it is important that you have genetic counseling in your local area to fully understand your chromosome results prior to pursuing preimplantation genetic testing. The technology used to perform PGD for chromosome rearrangements will also screen embryos for other sporadic aneuploidies in all 23 pairs of chromosomes. Of note, this testing is not able to distinguish normal embryos without the balanced rearrangement from normal embryos that carry the same

balanced chromosome rearrangement as the parent, or balanced embryos that result from uniparental disomy (UPD).

Procedure. During your IVF cycle, the embryologist (laboratory scientist) at your IVF center, will remove one or more cells from each of your embryos and send those samples to Genesis Genetics for testing. Your embryos never leave your IVF center. Genesis Genetics will perform the testing that your IVF Center requests and send a test report back to them so that your IVF doctor can decide, in consultation with you, which embryos should be transferred.

Test Method: The specimen submitted is required for isolation, purification, and amplification of DNA for molecular genetic testing by BAC Microarray or Next Generation Sequencing (NGS).

Test Results and Confidentiality: I understand that due to the complexity of DNA based testing and the important implications of the test results, these results will be reported only through my physician(s) or genetic counselor (where allowed) and that I must contact my provider to obtain the results of the test. In addition, the test results could be released to all who, by law, may request access to such data.

- I understand that if the PGS result is **positive (aneuploid)**, the embryo may have extra or missing chromosome material and the embryo may not be suitable for transfer.
- I understand that if the PGS result is **negative (euploid)**, the embryo may not have extra or missing chromosome material and the embryo may be suitable for transfer.

Limitations of Testing.

1. **Test Sample.** I understand that the test results are based on probabilities, and do not provide a 100% guarantee of either genetic status or manifestation. I understand that testing may not generate results and that an additional sample may be needed to obtain an accurate result. I understand that inaccurate results are possible due to: degraded samples, contamination of samples, inaccurate reporting of family relationships, or technical problems, but not limited to these causes.

2. **Delay in testing may make a fresh embryo transfer impossible.** PGS testing must be closely coordinated with the timing of the IVF cycle. There can be a delay in shipping the samples to Genesis Genetics (e.g. flight delays for the courier/shipper due to weather) or lab conditions may make testing impossible or may delay testing. In this case, your results may not be available in time for a transfer. The team at your IVF center may then have to freeze your embryos and wait for the test results. Genesis Genetics will not be responsible for these additional costs.

3. **Loss or Damage of Samples in Transport.** Though it is uncommon, loss or damage of samples in shipping can occur and would result in no test results being available from those embryo samples. Genesis Genetics cannot will not be held responsible for these errors.

4. **PGS involves testing only a few cells.** The sample provided to Genesis Genetics for testing is only a small portion of the embryo itself. Each cell of this early embryo may be slightly different; one may be normal and the one next to it may be abnormal. This is called chromosome mosaicism. Because PGS makes use of a limited number of cells, it is possible that the result obtained may not reflect the condition of the whole embryo. It is possible to report an embryo as normal when it is in fact abnormal and vice versa. Testing one cell is not even remotely similar to testing thousands or millions of cells from a blood, tissue, or amniocentesis sample. As a result, the PGS test is not as reliable as certain genetic tests that occur later on in development.

5. **Mechanical and Human Error.** All testing that takes place at Genesis Genetics is conducted by highly trained laboratory scientists using mechanical/electrical equipment. In spite of their best efforts, errors that result in the damage or loss of samples can occur. These may include (but are not limited to) equipment malfunction, failure of backup power sources, and damage to the sample during processing. Genesis Genetics works diligently to have systems in place to detect and prevent these types of errors. However, if such an error occurs, Genesis Genetics will only be responsible for the cost of testing performed at Genesis Genetics and not for your IVF cycle or any other cost.

6. **Spontaneous Pregnancy.** All females undergoing genetic testing as part of their IVF cycle should abstain from intercourse or use a barrier contraceptive throughout their IVF treatment in order to protect against conception. If a spontaneous pregnancy occurs, it defeats the purpose of the PGS test and could lead to the implantation of an untested embryo.

Other Risks or Special Circumstances in PGS Testing:

1. **The use of PGS for aneuploidy or translocation is not 100% accurate.** PGS testing using microarrays or NGS has a technical error rate of approximately 2%, as reported in published medical literature. Statistically, an incorrect test result will be obtained on 2 of every 100 embryos tested despite the fact that the test was performed correctly.

2. **Normal results on tests using PGS do not guarantee that a healthy pregnancy will ensue.** PGS testing is designed to detect large errors in chromosome numbers or rearrangement of large pieces of DNA. PGS will not detect unknown pathogenic changes in copy number smaller than 10MB. It cannot detect polyploidy. PGS cannot detect small errors, such as gene mutations, in the embryo. This means that PGS cannot detect inheritable diseases that are linked to very specific genes such as Cystic Fibrosis, Sickle cell anemia and Tay-Sachs disease. Families who carry these diseases require a different type of testing called preimplantation genetic diagnosis (PGD).

3. **The use of PGS does not eliminate the need for prenatal genetic testing.** Based on the error rates and limitations of PGS discussed above, it should be clear that PGS is a screening tool only. Prenatal diagnostic testing such as amniocentesis and chorionic villus sampling remain the most widely accepted methods of modern diagnostic testing. The sole purpose of PGS is to help identify what are believed to be the best embryos for transfer to the uterus. No technology, including this one, can guarantee that a healthy child, free of genetic defects, will result. The typical risk of a birth defect, in a child conceived naturally or with IVF, is around 3-4 percent. The purpose of this test is not to appreciably alter this number, but to aid the patient in getting pregnant.

4. **The Special Case of Gender Identification.** Just as PGS testing in general is not 100% accurate, neither is gender identification. Gender identification is technically difficult and requires experienced scientists to correctly interpret the data. The reported error rate for gender identification testing can be as high as 5% (5 of every 100 embryos with an incorrect result even when the test is performed correctly). Gender reports should be used by you and your IVF center as a guideline with the understanding that gender cannot be guaranteed.

5. **Genesis Genetics Can Only Perform and/or Report on the Testing That Is Ordered By Your Physician.** Based on the technology used to perform PGS, chromosomal abnormalities in the embryo may be detected as incidental findings to the test requested. Genesis Genetics cannot report these findings unless they are part of a test that was ordered by your physician. This can result in the transfer of abnormal embryos. For example,

if your physician orders gender identification *only*, the testing might indicate that a specific embryo also has a chromosome abnormality. However, Genesis Genetics can only report the gender of that embryo (by law) since your physician only ordered gender identification. That is, Genesis Genetics cannot report that the embryo is also abnormal.

6. **Sample storage.** While Genesis Genetics makes every effort to monitor all mechanical equipment and laboratory conditions, equipment failures and other laboratory events can occur that could result in the loss or irreparable damage of your samples (for example, floods, fire, equipment failure, etc.). Financial responsibility for samples lost or damaged will be limited to the cost of the genetic testing performed by Genesis Genetics and will not include the cost of the IVF cycle (s) or any other cost. Biopsy samples from embryos containing DNA and submitted for testing will be stored no longer than 60 days upon the completion of testing. These samples may be stored for longer periods of time if mandated by state or federal law or by appropriate accrediting organizations. Also, there is an opportunity for you to consent to a longer storage period time at the end of the Agreement. In all cases, the length of storage will be dictated by applicable law. Once testing has been completed, the samples may be used for quality control purposes or to validate or develop new or existing test methods.

7. **Receipt of Samples Before a Test is Approved.** Some tests performed by Genesis Genetics require mutation reports or other information from the family before we can determine if testing is possible in your particular case (e.g. translocation testing). Your IVF center should ***not*** submit samples for testing to Genesis Genetics until testing in your specific case has been approved. If samples are submitted before testing is approved, you will be charged for any processing of the samples that is needed in order to store the samples. If testing is not possible, you will not be charged for PGS and the samples will be discarded or shipped to another location of your choice. However, Genesis Genetics will not be responsible for the cost of your IVF cycle or any other cost.

8. **The Role of Your IVF Program Versus the Role of Genesis Genetics.** Genesis Genetics is not acting in any way as your physician; Genesis Genetics is acting solely as a reference laboratory performing testing at the order of your physician. Genesis Genetics can only be held responsible for the actual genetic testing that is performed in its laboratories. Genesis Genetics can only be held responsible for the actual genetic testing that is performed in its laboratories and Genesis Genetics will only be responsible for the cost of testing at Genesis Genetics and not for the IVF cycle or any other cost.

   Your IVF Center is responsible for managing your IVF cycle and the process of producing the embryos from which the samples are obtained, performing the biopsy, labeling the samples, placing them in the correct tubes for testing, sending them to Genesis Genetics, utilizing the test report to determine which embryos to transfer, determining which embryos to transfer and transferring the correct embryos. Genesis Genetics does not recommend the transfer of an embryo that has "No Result" as the embryo is untested and could result in the transfer of an abnormal embryo. Genesis Genetics does not recommend the transfer of an embryo that is abnormal. Genesis Genetics will not be held responsible for any adverse outcomes that result from the transfer of such embryo. It is likely that you will be undergoing other diagnostic and therapeutic care (for example: DNA or chromosome testing, reproductive care, etc.) at another institution and consent form(s) pertaining to that institution will be required. Any other informed consent from other providers does not supersede or replace the Agreement.

   Financial Considerations. I have been provided with separate written information about Genesis Genetics financial policies and changes. I understand and agree that my test results will not be released and new testing will not be conducted until all of my financial accounts are paid and current.

Further Information. Genesis Genetics will provide genetic counseling to Patient's prior to signing the Agreement when there is a translocation involved. Genetic counseling may also be available after the test. The genetic counseling that Genesis Genetics provides is limited to the PGS process and Genesis Genetics will not be able to act as a personal genetic counselor. Your physician may require further testing or additional consultations outside of Genesis Genetics.

Legal Issues.

Jurisdiction and Venue. By signing the Agreement, I agree that all legal claims arising out of the PGS treatment or the Agreement will be governed by the laws of the **State of Michigan.**

In addition, should there be any litigation as a result of the PGS procedure or the Agreement, such litigation or otherwise, shall be brought in the Circuit Court for Oakland County, Michigan or in the United States District Court for the Eastern District of Michigan.

Waiver of Jury Trial. I, after consulting or having had the opportunity to consult with legal counsel, knowingly, intelligently and voluntarily waive any right I may have to a trial by jury, in any litigation or dispute based upon or arising out of the Agreement or services provided by Genesis Genetics. I will not seek to consolidate any action in which a jury trial has been waived with any action in which a jury trial has not been waived.

Notices. All notices and other communications required or permitted under the Agreement will be in writing and will be deemed given when delivered personally or by registered or certified mail (return receipt requested), addressed as follows (or any other address that is specified in writing by either party):

If to Genesis Genetics:	Michigan Genetics, LLC 1380 E. Jefferson Ave. Detroit, MI 48207
If to Patient/Partner:	Address as provided to Genesis Genetics.

Interpretation. The use of the masculine in the Agreement includes the feminine and the neuter and vice versa; the use of the singular includes the plural and vice versa.

Assignment. No party may assign any of its rights or delegate any of its obligations under the Agreement without the prior written consent of the other party, except that any party may assign any of its rights and delegate any of its obligations under the Agreement to a wholly owned subsidiary. Any other purported assignment or delegation in violation of this section shall be void.

Successors and Assigns. The Agreement's rights, obligations, or benefits shall be effective on either parties successors or assigns.

Severability: Each provision of the Agreement is separate. In the event that any part of the Agreement is declared by the court, or other judicial administrative body, to be invalid or unenforceable, it will be invalid only to the extent of the invalidity, without affecting or impairing the validity and enforceability of the remainder of the section, subsection or other provisions of the Agreement.

Should Genesis Genetics alter, update or modify the Agreement before my testing has been conducted, I agree to execute the new consent agreement. I understand that my test results will not be released until the new consent

agreement has been received by Genesis Genetics. After the Agreement is signed, it may only be amended, modified, or supplemented by an agreement in writing signed by each party hereto, or an authorized representative thereof.

SIGNATURE: By my signature, I acknowledge that I have been informed about this laboratory testing, have had an opportunity to ask questions and hereby consent to this laboratory testing. I have had the opportunity to review the Agreement with counsel of my choosing. I understand that if I have any questions about the genetic testing of my embryos, the questions should be directed to a genetic counselor at Genesis Genetics (Phone: 313-579-9650). Genesis Genetics will not release test results until the Agreement is fully executed and has been returned to Genesis Genetics.

PATIENT SIGNATURE	**PARTNER SIGNATURE**
_____	_____
Signature of Patient	Signature of Partner
_____	_____
Printed Name	Printed Name
_____	_____
Date	Date

NOTE: The Center must receive a correctly executed version of the Agreement before results are released.

It may be beneficial for Genesis Genetics to retain your DNA specimen for a period longer than 60 days in the event that you need additional testing. Accordingly, I acknowledge that Genesis Genetics may use and store the DNA specimen after the testing for a period longer than 60 days.

PATIENT SIGNATURE	**PARTNER SIGNATURE**
_____	_____
Signature of Patient	Signature of Partner
_____	_____
Printed Name	Printed Name
_____	_____
Date	Date

HIPAA Authorization and Information

Your physician is required to provide information regarding the Health Insurance Portability and Accountability Act including a HIPAA authorization policy and Notice of Privacy Practices. Genesis Genetics serves as an indirect health care provider to your physician or IVF clinic and complies with all HIPAA regulatory requirements. Further questions regarding HIPAA disclosure rules and regulations can be obtained from www.hhs.gov.hipaa and www.hhs.gov/ocr/privacy. Genesis Genetics will provide a copy of Notice of Privacy Practices upon request from the patient.

GENESIS GENETICS, LLC /s/ _____

NHFC
4 Columbus Circle, 4th Fl.
New York, NY 10019
T: 212.517.7676
F: 212.489.6294

Genetic Testing Program Fees-Genesis Genetics

All New Hope Fertility Center Genetic Testing fees must be paid in full before samples are sent for genetic testing to Genesis Genetics
新希望基因检测费用必须在周期开始时付清。

NGS or aCGH Biopsy and Testing Fee （aCGH 或 NGS 活检)	Per embryo cost (每個胚胎) $750.00 (includes assisted hatching) 包括胚胎辅助孵化

Insurance: NHFC's billing representative can provide you with any applicable CPT codes for insurance claim filing purposes.
保险：新希望代表可以提供保險 CPT 號碼。

I received the financial policy for the Genetic Testing Program Program/ 我知道所有基因检测费用:

- I understand that I am responsible for all fees associated with New Hope Fertility Center/ 我（患者）必须支付所有费用。
- I understand that all fees must be paid in full before samples can be sent for testing/ 所有费用必须在周期开始时付清。
- No refund will be issued once biopsy completed/ 當活检完成時，所交款项不予退还。
- To obtain a refund of other fees paid, please speak with a billing representative/ 如果我（患者）要求退款， 請联系新希望。

_____	_____	_____
Patient's Name (Print)/ 姓 名	Signature/签 名	Date/日 期
_____	_____	_____
Partner's Name (Print)/ 伴侶 姓 名	Signature/签 名	Date/日 期

Our billing department is open Monday - Sunday from 7:00am - 5pm. To contact our billing department, contact information is listed below.
新希望工作时间是星期一到星期日从 7:00 到 17:00。我们的客户服务热线是：

***Billing Department**

212-969-7430 - billing@nhfc.com

Staff:
_____