INFORMED CONSENT FOR PGT-A

3015 Williams Drive | Fairfax, VA 22031 | 703-698-7355 | www.givffertility.com

INSTRUCTIONS:

This consent reviews the **Preimplantation Genetic Testing for Aneuploidy Screening (PGT-A)** process, including a description of the test, its benefits, and its limitations.

- Read this informed consent document completely before signing the **Acknowledgement and Acceptance of Informed Consent** on page 4. If you have any questions, please speak with your doctor or genetic counselor.
- Do not make any additions or deletions to the consent.
- Testing **cannot** be started until all consents are signed in front of a Genetics & IVF (GIVF) staff member or a Notary Public, or through a GIVF-Initiated ID Verified DocuSign, and returned to GIVF

I/We, the undersigned patient/intended parent, and partner (if applicable), have discussed PGT-A with a Reproductive Geneticist and/or Genetic Counselor. The following benefits and limitations of aneuploidy screening on embryos have been explained to me/us.

BENEFITS:

1. PGT-A is a genetic test to identify whether embryos have a normal or abnormal number of chromosomes. An abnormal number of chromosomes is called aneuploidy. PGT-A has also been termed PGS (preimplantation genetic screening) or PGD (preimplantation genetic diagnosis) for aneuploidy.
2. The test determines which embryos are chromosomally normal (euploid) and the results can be used to help select which of the embryos to transfer to the uterus. It is known that one of the major causes of failed implantation and early miscarriage is extra or missing chromosomes in the embryo. By selecting the best embryos for transfer, this testing may decrease the miscarriage rate and increase the implantation rate. This results in an overall higher chance for a successful ongoing pregnancy.
3. The technology used to perform this testing is called next generation sequencing (NGS). Approximately 98% of chromosome abnormalities are identified by this testing. Examples of chromosome abnormalities and expected abnormality rates have been described to me/us.
4. Instead of transferring multiple embryos, often only a single tested embryo is transferred to the uterus at one time, reducing the risk for multiple gestations (twins and triplets) that are associated with higher rates of fetal and obstetrical risks.
5. Sex chromosome information is included in the testing performed and will be included in my/our medical file at GIVF. It has been explained to me/us that sex chromosome information can be shared or withheld at my/our choosing.

LIMITATIONS:

1. A misdiagnosis is possible. As with all clinical testing, there can be biological, technical, or human reasons that can result in an incorrect test result. The most likely cause of a misdiagnosis in embryos is *mosaicism*, or errors in the early division of an embryo resulting in cells with different genetic content

within the same embryo. In a mosaic embryo, the biopsied cells may have a different test result than the rest of the embryo. Mosaicism is handled differently in every laboratory. If the PGT laboratory at GIVF identifies mosaic embryos during the testing process, they will be classified as "normal" or "abnormal" based on internal established thresholds.

2. Testing yields no chromosomal information in approximately 2% of embryos that are biopsied. These embryos are classified as "***undetermined***", in that it is unknown if the embryo is chromosomally normal or abnormal, and unknown if the embryo is male or female. It does not necessarily indicate a problem with the embryo – it is simply a known limitation of testing a small amount of genetic material. Embryos may be "undetermined" for various reasons including poor embryo quality, loss, or damage of the genetic material during the testing process, failure of the testing equipment or human error. At GIVF, "undetermined" embryos may be used for attempting pregnancy if desired. It may also be possible to attempt repeat biopsy and repeat analysis to yield a PGT-A result. The rebiopsy attempt is often successful in determining the embryo's chromosome status; however, it is possible that the embryo may not be able to be rebiopsied, may not be able to be refrozen for future use, or could be "undetermined" again after retesting.
3. Testing cannot identify embryos with an extra set (or sets) of ***all*** the chromosomes. This is called triploidy (three sets) or tetraploidy (four sets), whereas the normal number of sets to have is two (one set from the egg and one set from the sperm). Pregnancies with these abnormalities frequently result in miscarriage.
4. Missing or extra pieces of chromosomes will be reported if identified, however, very small segments below the level of resolution may not be identified. These types of abnormalities are not age-associated. They can be inherited or sporadic and can cause both physical and developmental fetal abnormalities.
5. Specific genetic diseases such as cystic fibrosis, Fragile X syndrome, or muscular dystrophies are not included in PGT-A. For couples at risk for these or other single gene diseases, a different genetic test on embryos is available which is used along with PGT-A.
6. Some conditions, such as autism, bipolar disorder, and diabetes, are believed to be due to a combination of genetic and environmental factors. Since the exact causes cannot be defined, testing for these conditions and other conditions where the cause is unknown is not possible on embryos or pregnancies.
7. Even when chromosomally normal, all pregnancies have a 3-4% chance for a physical birth defect such a heart defect or a cleft lip. Ultrasound examinations during an ongoing pregnancy can evaluate fetal physical development.
8. PGT-A is not intended to replace chromosome testing options during pregnancy, but it does reduce the risk of having an abnormal pregnancy. Fetal ultrasound, first trimester screening, cell-free DNA screening, chorionic villus sampling (CVS), and amniocentesis are available tests in an ongoing pregnancy. Women are encouraged to consider all their genetic testing options to determine which tests are appropriate for them personally.

THIS IS WHAT I/WE CAN EXPECT FROM IVF WITH PGT-A:

1. To reduce the risk of misdiagnosis, it is recommended that **Intracytoplasmic Sperm Injection (ICSI)** be used for fertilization of embryos that will undergo PGT-A testing. ICSI involves the direct injection of a single sperm into the interior of an egg, reducing the possibility of contamination from extraneous sperm. PGT on embryos created without the use of ICSI may be at increased risk for misdiagnosis. As a standard practice, embryos created at GIVF that will undergo PGT-A testing are created using ICSI. ***Please refer to the "*Intracytoplasmic Sperm Injection*" section of the INFORMED CONSENT FOR ASSISTED REPRODUCTION Information Packet.***
2. PGT-A is possible only on embryos that reach an appropriate stage of development, called a ***hatching blastocyst****,* after 5-7 days of embryo development. It is possible to have no embryos progress to a *hatching blastocyst*. If there are no embryos that reach this stage, PGT-A will not be performed.
3. To encourage embryo development to the stage they can be biopsied, **assisted hatching** is performed in our embryology laboratory on the third day of embryo development. During the assisted hatching procedure, embryologists make a small opening in the outer shell of the embryo (zona pellucida), using a small microscope-mounted laser. ***Please refer to the "Assisted Hatching" section of the INFORMED CONSENT FOR ASSISTED REPRODUCTION Information Packet.***
4. For appropriately developing embryos, a biopsy, or removal of approximately 3-8 cells from an embryo, is performed. The cells are removed from the trophectoderm, which becomes membranes and the placenta, not from the cells that will develop into the fetus. Removal of cells from the trophectoderm is considered safe. Data from over 25 years of PGT in humans, including thousands of live births, indicate that removing cells from early embryos does not lead to an increase in birth defects or chromosome disorders.
5. Embryos that undergo biopsy are **cryopreserved** (frozen) to maintain the embryos while testing is completed. The cells that are removed by the biopsy procedure are used for the PGT-A analysis. It is not possible to test the entire embryo. If a suitable embryo is found for transfer it will be thawed at a later time for a frozen embryo transfer (FET). Although rare, the cryopreservation process (freezing, storage, and thawing) can damage or destroy some or all cryopreserved embryos. ***Please refer to the "Cryopreservation" section of the INFORMED CONSENT FOR ASSISTED REPRODUCTION***
6. Testing is performed on-site in the PGT laboratory at Fairfax Diagnostics, a division of GIVF.
7. A GIVF genetic counselor or physician will contact me/us directly with test results. Sex chromosome information will be available at that time upon request.
8. Embryos with a normal (euploid) or undetermined result may be considered for use in a frozen embryo transfer (FET) cycle to attempt pregnancy. GIVF will not transfer an embryo with an abnormal PGT-A (aneuploid) result.
9. I/We can cancel PGT-A during the IVF cycle prior to embryo biopsy, after speaking with our physicians. The option to transfer non-tested embryos may be discussed with the physician.
10. Embryo banking, or combining embryos from more than one IVF cycle, for a combined single PGT analysis may be considered after consultation with our physicians.

NO GUARANTEES:

GIVF cannot and does not guarantee that:

- An embryo will be available for PGT-A or for embryo transfer; or
- That the PGT-A results will be acceptable to me/us; or
- IVF with PGT-A will result in a pregnancy, or that a pregnancy, if achieved, will result in a live birth or normal birth outcome, or in the birth of a child of the desired gender.

ACKNOWLEDGEMENT AND ACCEPTANCE OF INFORMED CONSENT

I/We have read and understood the above and have been fully advised of the purpose, limitations, and benefits of PGT-A testing. This information has been supplemented by my/our consultation with my/our medical team. I/We have had the opportunity to discuss PGT-A with a physician or genetic counselor and have had our questions addressed.

I/We understand this Informed Consent for PGT-A will remain in effect until one of the following events occurs: one (1) calendar year has passed from the date of signature; death of patient; or written notice to GIVF of withdrawal of consent by the patient and/or the patient's partner, if applicable.

PATIENT/INTENDED PARENT

Signature:_____

Printed Name:_____

Date:_____

Type of Picture Identification viewed:

- ☐ Driver's License
- ☐ Passport
- ☐ Other: _____

PARTNER: ☐ N/A

Signature:_____

Printed Name:_____

Date:_____

Type of Picture Identification viewed:

- ☐ Driver's License
- ☐ Passport
- ☐ Other: _____

GIVF Witness Name: _____ Signature: _____

Title: _____ Date: _____

Consents signed outside the Practice must be notarized and dated

PATIENT:

City/County of_____

State/Commonwealth of _____

The foregoing instrument was acknowledged before me this _____ day of _____, 20 _____ by _____ (Name of person seeking acknowledgment)

Notary Public's signature: _____

Notary registration number: _____

My commission expires: _____

PARTNER: ☐ **N/A**

City/County of_____

State/Commonwealth of _____

The foregoing instrument was acknowledged before me this _____ day of _____, 20 _____ by _____ (Name of person seeking acknowledgment)

Notary Public's signature: _____

Notary registration number: _____

My commission expires: _____