Karande & Associates, S.C. doing business as

InVia Fertility Specialists

Subspecialty Care in Reproductive Medicine

PREIMPLANTATION GENETIC DIAGNOSIS (P.G.D.) OF HUMAN EMBRYOS FOR ANEUPLOIDY SCREENING OR GENETIC RISK

We, _____, understand that Preimplantation Genetic Diagnosis (P.G.D.) of human embryos is an analysis done prior to the implantation of human embryos into the uterus and is performed as a way to diagnose embryos at increased risk for chromosomal or gene specific conditions. While P.G.D. with I.V.F. can be done for the purpose of gender selection only, this is currently not considered an appropriate use of medical resources by InVia Fertility Specialists, which follows guidelines expressed by the Ethics Committee of the American Society of Reproductive Medicine (A.S.R.M.). We fully understand the process of I.V.F. in conjunction with the diagnosis of the genetic condition for which P.G.D. analysis is being sought. In our case, testing is performed for:

_____.

P.G.D. testing is offered to couples that seek to screen their embryos for common chromosomal abnormalities or to diagnose a specific genetic disorder prior to implantation. Am embryo biopsy is the process by which a cell(s) is(are) removed from the embryo for genetic analysis. The biopsied embryo will be cultured in the laboratory while the diagnosis is being performed on the cell. P.G.D. combines the following technologies:

- In-Vitro Fertilization (I.V.F.)
- Micromanipulation and Embryo Biopsy
- Genetic analysis of the biopsy material for potentially abnormal gene/chromosomes.
- Uterine transfer of the potentially normal embryos to the female patient.

P.G.D. testing may have been requested due to the determination that there is an increased risk in the family of conceiving a child with the above-described genetic disorder. This increased risk is known because of a family history and/or as a result of standard genetic screening for the disease. We understand that this genetic testing method cannot predict other birth defects or genetic disorders or necessarily even all cases of the disorder, described above, for which P.G.D. is performed. The objective of the P.G.D. testing will be to test for the specific disease for which we know our offspring to be at risk.

For couples requesting aneuploidy screening, P.G.D. incorporates a technique which identifies the loss or presence of extra chromosomes. Humans have 23 pairs of chromosomes. At this time, P.G.D. technology can accommodate the screening of 5-7 chromosomal pairs. Hence, P.G.D. allows screening for those common chromosomal abnormalities that can result in the birth of an affected fetus. We understand this genetic screening cannot predict other birth defects, chromosomal abnormalities, or genetic disorders. We also understand that an error in the diagnosis can occur (approximately 5%) despite proper utilization of all laboratory techniques.

With aneuploidy screening, the gender will be determined as part of the diagnosis. **If available**, we prefer that the embryos diagnosed by P.G.D. to be (*circle choice*):

MALE FEMALE

be selected for transfer.

We understand I.V.F. techniques are necessary in order to undergo P.G.D. testing on embryos and we, therefore, agree to participate in the I.V.F. program. We also understand that our I.V.F. cycle will be conducted in accordance with InVia Fertility Specialists guidelines as outlined in a

separate consent, entitled “Assisted Reproductive Technologies (A.R.T.) Program” and coordinated amongst INVIA FERTILITY SPECIALISTS physicians, embryologists, and the laboratory performing the biopsy, analysis, and diagnosis of P.G.D. testing.

We understand that the actual P.G.D. testing may be performed at the INVIA FERTILITY SPECIALISTS laboratory and/or in coordination with another outside laboratory. We acknowledge that INVIA FERTILITY SPECIALISTS, nor any of its employees can be responsible for the outcome of such testing. For this I.V.F./P.G.D. cycle, the diagnosis will be performed by: _____.

We have been fully informed of alternative options available to us to avoid having a child with the aforementioned genetic condition, which may include:

- Electing to not have any children
- Adoption
- Artificial insemination with donor sperm (tested negative for the genetic condition)
- Donor oocytes from a donor (tested negative for the genetic condition)
- Prenatal screening by means of Chorionic villus sampling or amniocentesis followed by termination of affected pregnancies

The purpose of this procedure is for us to obtain a pregnancy and to have a child that does not have the genetic condition for which we are at increased risk. INVIA FERTILITY SPECIALISTS physicians and embryologists exercise the right to use reasonable medical judgment to determine if the sperm, oocytes, or embryos are non-viable or otherwise not medically suitable for use or embryo transfer. INVIA FERTILITY SPECIALISTS is not obligated to transfer these embryos at any point in the future if medical evidence and/or experience indicate the risk of transfer outweighs the benefits.

We understand that the following are risks of P.G.D. testing and that these risks are in addition to the risks of an I.V.F. procedure, as outlined in a separate consent entitled “Assisted Reproductive Technologies (A.R.T.) consent.:

- A human error, mechanical problem, and/or accident in the laboratories may result in the loss or damage to the egg, sperm, or embryos
- The specific genetic test may fail to correctly diagnose the embryos being screened
- The genetic testing will be performed on a single cell. P.G.D. testing is fairly new and not widely available. There is a possibility that a misdiagnosis may be made on any one of the embryos prior to intrauterine transfer and that the actual process of testing may adversely affect the development of the fetus
- The risk of Ovarian Hyperstimulation Syndrome (O.H.S.S.) may be greater in a fertile female than a female with infertility
- The embryos may not survive freezing or thawing if cryopreserved

Following I.V.F. and P.G.D. there **may** be excess high quality embryos available other than those selected for intrauterine transfer. In this situation, we understand we must direct INVIA FERTILITY SPECIALISTS to handle the excess embryos by the option(s) selected below (*both partners must select/initial the same option(s)*).

Option 1: The **cryopreservation** of embryos (*circle a, b, or c*):

a) Diagnosed as free of the genetic condition being tested for by P.G.D.
b) Diagnosed as “normal” for the chromosomes being tested, **regardless** of the gender diagnosis
c) Diagnosed as “normal” for the chromosomes being tested and with the gender diagnosed as (*circle one*):
   MALE **FEMALE**
   See options 2, 3, & 4.

We understand that there is limited worldwide data available on the success of biopsied embryos surviving a thaw cycle. We are also aware that we will have to pay the cryopreservation fee and monthly storage fees and will have to sign the *Cryopreservation of Human Embryos Consent*.

Female: _____ Male: _____

We understand that if we chose from the following options that we relinquish parental rights to those specified embryos.

Option 2: The **disposal** of all embryos/embryos of the unselected gender (*circle one*) in an ethically accepted manner according to the INVIA FERTILITY SPECIALISTS Guidelines and the American Society of Reproductive Medicine Ethical standards.

Female: _____ Male: _____

Option 3: The use of all embryos/embryos of the unselected gender (*circle one*) for Institutional Review Board approved medical **research** according to the American Society of Reproductive Medicine Ethical Standards.

Female: _____ Male: _____

Option 4: The **donation** of all embryos/embryos of the unselected gender (*circle one*) for use by an anonymous recipient in accordance with the regulations and policies in force at INVIA FERTILITY SPECIALISTS at the time of donation. We understand that both donor parties must complete a donor profile. If the embryos are accepted for embryo donation, both donating partners will need to have certain blood tests performed, at no charge to them. We understand that INVIA FERTILITY SPECIALISTS will notify us what blood tests are necessary and when they will be performed. We also understand that if we fail to have all blood tests performed within 90 days from the time we are requested to have them, all of our embryos will be destroyed according to INVIA FERTILITY SPECIALISTS Guidelines and the American Society for Reproductive Medicine Ethical Standards. We furthermore understand that if INVIA FERTILITY SPECIALISTS determines that the embryos are not acceptable for use in the Embryo Adoption Program, they will be disposed of, following the INVIA FERTILITY SPECIALISTS Guidelines and the American Society for Reproductive Medicine Ethical Standards.

Female: _____ Male: _____

We understand that the financial responsibility for P.G.D. is ours and that the costs incurred are in addition to standard charges with I.V.F.. Some insurance companies may not pay for the costs involved with P.G.D.. We therefore are expected to pre-pay all P.G.D. charges prior to oocyte retrieval. In this case of P.G.D., the costs are expected to be $ _____, made payable to _____. In the event of an excessive number of embryos being available for biopsy and diagnosis, additional charges of approximately $ _____ may result.

INVIA FERTILITY SPECIALISTS understands the importance of confidentiality in relation to your care. Every effort will be made to maintain the confidentiality of your medical history, records, and the outcome of the P.G.D. analysis within legal limits; however, absolute confidentiality cannot be guaranteed. Please note that your names will not be released without specific written consent. Any data collected from this program will be presented in scientific format only if your anonymity can be maintained.

In the event of injury resulting from the process of I.V.F. and/or P.G.D. analysis, no financial compensation will be provided. We acknowledge that P.G.D. analysis is performed at our request and we voluntarily request that INVIA FERTILITY SPECIALISTS proceed with the plan as

outlined above. We understand that we may revoke this consent at any time prior to P.G.D. testing being initiated.

All of our questions regarding this consent on P.G.D. have been answered. Each of us has read the consent and acknowledges receipt of a copy of this statement.

_____	_____	_____
Date	Signature of Female Patient	Female Name – Print
_____	_____	_____
Date	Signature of Partner	Partner Name - Print

As one of the members of INVIA FERTILITY SPECIALISTS, by my signature indicate that the foregoing consent was read, discussed, and signed in my presence.

_____	_____	_____
Date	Signature of Witness (Female Patient)	Witness Name – Print
_____	_____	_____
Date	Signature of Witness (Partner)	Witness Name – Print

NOTE: If you or your partner is unable to have this consent witnessed by a staff member or FULLY UNDERSTAND THE CONSENT, please notify the medical staff. We will provide you with further information and a witness. If you wish to sign the consent outside of INVIA FERTILITY SPECIALISTS, please have the consent notarized.

State of _____, County of _____, I, the undersigned, a Notary Public in and for the said County in the State aforesaid DO HEREBY CERTIFY that

_____
(Female Patient/ Partner)

personally known to me as the same persons whose names are subscribed to the foregoing document appeared before me this day in persons, and acknowledged that he and she signed, sealed, and delivered the said document as his and her free and voluntary act, for the use and purposes therein set forth.

Given under my hand and official seal this _____ day of _____, 20_____.

Commission expires on _____, 20_____.

_____
(Notary Public)

(Notary Seal)