PATIENT INFORMED CONSENT

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www.PGDscience.com

Embryo Biopsy and **Preimplantation Genetic Determination (PGD)**

I / we, _____(please print legibly), the undersigned, request and consent to embryo biopsy and preimplantation genetic determination (PGD) of our embryos. These are investigational procedures requiring removal of one or more cells (blastomeres) from embryos. The removed cells are evaluated to determine specified chromosomal or genetic status, of each biopsied embryo. After evaluation of each embryo, some or all embryos deemed appropriate for establishing the pregnancy will be transferred into the uterus by standard methods. Among other attributes, PGD has been shown to lessen the chance of having a child with genetic or chromosomal abnormalities, as well as to lower miscarriage rates due to such abnormalities. PGD is being requested at this time to evaluate the status of the embryos for _____(refer to "Request For Preimplantation Genetic Testing Services" form provided to your physician specialist, to be filled out and faxed to the PGD Science, Inc. on your behalf).

Procedures:
It is assumed the cell(s) that is removed from the embryo is representative of the whole embryo. This is true in greater than 90% of the time.
PGD is an adjunctive procedure to In Vitro Fertilization (IVF). Therefore, controlled ovarian stimulation, egg retrieval, fertilization and embryo development occur as usual with IVF (procedure and risks discussed on IVF consent). PGD starts with embryo biopsy which can be performed on day 3, day 4 or day 5 of development. Day 3 embryo consists of a shell (zona pellucida) containing 4 to 10 cells called blastomeres. On day 4 embryo is usually morula stage which may contain more than 16 cells. Day 5 embryo can develop to the blastocyst with more than 100 cells. An embryologist uses micromanipulation techniques to create a small hole in the shell. One (occasionally two) of the cells (of Day 3 embryo, a few cells from Day 5 embryo) is then removed from the opening in the shell. The cells inside the embryo are undifferentiated; therefore, removal of one or a few cells from the embryo should not affect development of the embryo.

Fluorescence in situ hybridization (FISH) is a separate more commonly applied technique used to identify specific chromosomes. FISH is used to detect the number of a set of chromosomes present inside the blastomeres. In order to determine the numerical chromosomal content of the cell, the nucleus must be isolated. This process is called fixation. The cell is placed on a glass slide and treated with chemicals to wash away the cytoplasm containing the cellular machinery while affixing the nucleus containing chromosomes onto the slide.

A probe is a small molecule designed to bind to a specific chromosome and fluoresce ("glow") when exposed to UV light. Probes for the desired panel of chromosomes are allowed to bind to the chromosomes on the glass slide. The fluorescence results are used

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to tally the number of chromosomes present inside the cell. All of the chromosomes in a cell cannot be evaluated due to time and technology constraints. The chromosomes evaluated are the ones which most frequently lead to abnormal pregnancy or miscarriage. This type of analysis constitutes the majority of PGD performed clinically.

Embryo biopsy, analysis of the biopsies blastomeres and delivery of the completed study to the physician can take from 8 hours to 2 days, depending on the study.

The results of these studies will determine which embryos are selected for transfer. The embryos will be transferred back to the recipient patient's uterus 4-7 days following egg retrieval, or at an unspecified date if the embryos are cryopreserved (frozen) for future use.

Possible undesirable outcomes from PGD:
IVF implementing PGD has resulted in over one thousand live births worldwide. Although there is no apparent increase in congenital defects reported, the procedure adds additional risks to IVF. These additional risks include but are not limited to:

1. Damage to the embryo during the removal of the cell(s)
2. Inability to obtain a cell for analysis during the biopsy
3. No nucleus present in the cell or poor fixation of nucleus
4. Inadequate binding of probes to the chromosomes
5. Difficulty or error in detection or interpretation of probes (e.g. overlapping signals) resulting in inconclusive results
6. Mosaicism (combination of normal and abnormal cells) in the embryo leading to the genetic material of the cell not being representative of the genetic material in the embryo
7. No embryo(s), normal or abnormal, available for transfer
8. Mis-selection of embryo(s) for transfer into the uterus
9. Implantation failure

We understand that embryo biopsy and PGD are relatively new procedures. Current data indicate the potential for misdiagnosis to be in the range of 10 percent. This includes false positives (when a normal embryo is diagnosed as abnormal) and false negatives (when an abnormal embryo is classified as normal). Due to the possibility of error with PGD, we strongly advise further prenatal genetic testing with amniocentesis or chorionic villus sampling (CVS) as indicated for confirmation of PGD results during pregnancy.

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I / We understand that our physician may recommend transfer of some or all of the PGD-evaluated embryos. We understand that if a multiple pregnancy occurs, further genetic testing during pregnancy becomes more difficult and at times not possible to carry out.

I / We do jointly and severally release and forever discharge PGD Science, Inc., and each of its divisions, employees, officers, physicians, agents, successors, and assignees from any and all claims, demands, costs, expenses and loss of services incurred as a result of the physical or mental nature of any child or children produced using these procedures.

I / We certify that this form has been fully explained to us and we have read it or have had it read to us, and that we understand its contents. We acknowledge that we have been afforded the opportunity to ask questions, and those questions have been answered to complete satisfaction, and hereby consent to the procedures enumerated herein:

_____ dated _____/_____/_____
Patient signature

_____ dated _____/_____/_____
Partner signature

_____ dated _____/_____/_____
Witness Signature

I have consulted with and explained the contents of this consent form to the participant(s):

_____ dated _____/_____/_____
IVF Physician