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BOARD CERTIFIED REPRODUCTIVE ENDOCRINOLOGY
AND INFERTILITY

INFORMED CONSENT FOR IVF AND IVF LABORATORY PROCEDURES

Overview

Eggs are removed from the ovaries of a female (oocyte retrieval) and are placed in a laboratory setting. Sperm are added to the eggs using various techniques (fertilization). Fertilized eggs (zygotes) are placed in special growth promoting solutions (media). The zygotes undergo a process of cell division to form embryos (embryo culture). Embryos are then placed in the uterus in the hopes of producing a pregnancy (embryo transfer).

Methods of fertilization

- **Standard insemination**

The eggs and sperm are placed in close proximity in a small amount of growth media. The sperm are allowed to use the normal mechanisms for attaching to and penetrating an egg.

- **Intracytoplasmic sperm injection (ICSI)**

A single sperm is isolated and drawn into a specially designed glass pipette with a sharp tip. The pipette is inserted through the wall of the egg into its center (the cytoplasm). The sperm is released and the pipette is withdrawn. This technique was initially performed for couples in whom severe male factor is thought to be a contributing cause for infertility or previous treatment failures. Today, many programs opt to use ICSI to reduce the risk for spontaneous failed fertilization

Embryo culture

The developing embryo is in need of various substances for nutrition. Some of these substances are provided by the solution that the embryos are grown in (media). At different stages of development, the embryo has different needs so different media may be used. **Media may contain biologically derived materials.** During this time, the embryos are kept at a controlled temperature and atmosphere in an incubator. Embryos are inspected during this time to assess for normal development. Currently, it is possible to culture embryos for five to six days at which time they may reach the blastocyst stage.

Assisted Hatching (AZH, zona drilling, hatching)

The early embryo is surrounded by a protein shell called the zonae pellucidae. Before the embryo can attach itself to the wall of the uterus, the embryo must break out of this shell (hatching). There is some evidence that creating a small gap in the zonae will increase the likelihood for implantation. Gaps can be created by applying chemicals to dissolve the zonae or by mechanical means.

Preimplantation Genetic Diagnosis (PGD)

The study of the genes or chromosomes of an embryo in the laboratory setting prior to transfer to the uterus. **The techniques related to PGD are still considered investigational. We encourage all patients who have undergone PGD to have prenatal testing, as this is the current standard of care.**

- **Polar Body Biopsy** The first polar body is produced from the division of the egg after the final injection of hCG is given. Upon penetration of the egg by the sperm (fertilization), but prior to the joining of the sperm's genetic material with the egg's genetic material, the egg undergoes another cell division, producing the second polar body. Once implantation occurs, the polar bodies disintegrate and are not part of the developing fetus. By testing the first and second polar bodies, the genetic make-up of the egg, and maternal genetic contribution in the resultant embryo, can be determined. Removal and genetic analysis of the polar bodies may occur on the day of aspiration and/or the next day.
- **Blastomere Biopsy** (also known as embryo biopsy) Following fertilization, the zygote begins to divide. On the third day following the egg retrieval, normal embryos should be at the blastomere stage (4 to 8 cells). A cell may be carefully removed for genetic analysis. After removal of the cell(s), the developing embryo is placed back into the culture dish and genetic analysis is performed separately on the removed cell(s). At this early point of embryo development, all of the cells are equivalent and thus, removal of a cell from the embryo at this stage does not appear to remove anything critical for normal development. The embryo compensates for the removed cell and should continue to divide following blastomere biopsy.
- **Trophoblast Biopsy** Trophoblast biopsy is the newest technique for obtain cell from a developing embryo for genetic testing. As an embryo is developing, it continues to divide. In healthy embryos, by the 5th day of development, the embryos has divided into approximately 100 cells and forms a hollow fluid filled

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sphere. The embryo at this stage is known as a blastocyst. A blastocyst is composed of two cell types. The inner cell mass is a small clump of cells that go on to form the fetus. The majority of cells (which make up the sphere) are called trophoblast cells. The trophoblast cells will eventually go on to form the placenta and other non-embryo tissues. The advantage of trophoblast biopsy is that several cells can be obtained without affecting the development of the embryo. By obtaining several cells, more genetic information is available. This may increase the accuracy of the results.

Risks during IVF and laboratory procedures

- *A woman may have an insufficient response to medications to allow for egg retrieval.*
- *Upon egg retrieval, eggs may not be obtained from every follicle aspirated. Occasionally, no eggs may be obtained.*
- *The embryologist may fail to identify eggs from the follicular fluid*
- *The eggs retrieved may be immature or abnormal and therefore unusable.*
- *The male partner may fail to produce a semen specimen or produce sperm of sufficient quantity for fertilization*
- *Despite obtaining eggs and sperm, the eggs may fail to fertilize or fertilize normally and therefore be unusable*
- *The eggs or embryos may be damaged from micromanipulation procedures (ICSI, AZH, PGD)*
- *The embryos generated may fail to develop (cleavage arrest) or fail to develop normally*
- *Loss or damage to eggs, sperm or embryos may occur as a result of laboratory and clinical handling, equipment failure or acts of god*
- *The physician may fail to transfer the embryos into the uterus.*
- *Apparently normal embryos may fail to implant normally in the uterus after uterine transfer.*

We acknowledge that we have read the above consent in its entirety and have had any questions answered completely and to our satisfaction.

We understand the risks, consequences, and potential benefits of in-vitro fertilization.