In Vitro Fertilization Info & Consent

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DESCRIPTION

This document informs the Intended Parent(s) about the IVF process in detail, including the risks. It then asks the Intended Parent(s) to consent to this therapy with its risks.

TARGET

* All Intended Parents undergoing IVF; single or couples

RELEASE NOTES

* This is the 4th revision of this document
* Added language regarding mosaicism
* Added freezing and PGT information
* Shortened where possible

TO DO

* Modify this document according to local needs and preferences.
* Get legal review to assure conformance with State and local laws and regulations
* Delete this page

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In Vitro Fertilization

Information and Consent

**IVF Cycle Plan**

Inseminate all eggs? o Yes o No (limit \_\_ eggs)

Intravaginal culture o Yes o No

Utilize ICSI (intracytoplasmic sperm injection)? o Yes o No

Freeze remaining embryos? o Yes o No

Discard abnormal non-viable embryos? o Yes o No

Number of embryos to transfer? o 1 o 2 o 3 or more

Allow development to? o Day 3 (cleavage)

o Day 5 (blastocyst)

Genetic testing?

o PGT-A (genetic testing for aneuploidy)

o PGT-M (genetic testing for disease)

o PGT-SR (genetic testing for structural rearrangement)

Limit number biopsied? o No. o Yes, to \_\_\_ embryos

If all embryos frozen, why?

o Fertility preservation (long term banking (> 1 year)

o Deferred transfer (short term banking (< 1 year)

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Intended Parent A:**

Last Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ First Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date of Birth: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ID#\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Cell phone: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Intended Parent B:**

Last Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ First Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date of Birth: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ID #\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Cell phone: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

In Vitro Fertilization Process & Risks

An IVF cycle typically includes the following steps or procedures:

* Taking medicine to grow several eggs at once
* Removing the eggs from the ovary or ovaries
* Combining eggs and sperm (insemination)
* Growing any resulting fertilized eggs (embryos) in the lab
* Placing ("transfer") of one or more embryo(s) into a uterus
* Taking hormone medications to support pregnancy

Sometimes, other IVF steps may be included, such as:

* Injecting individual sperm into each egg, called intracytoplasmic sperm injection (ICSI)
* Freezing of eggs or embryos not transferred to the uterus
* Genetic testing of the embryos for abnormalities (preimplantation genetic testing)

Growing multiple eggs

* The success of IVF is improved by growing multiple eggs at once.
* Some women can grow many eggs, and others very few.
* The medications used to grow more eggs can be injections, pills, or both.
* Other medications are used to prevent premature ovulation.

Various medications are used to stimulate eggs to grow. Some can be taken as pills, but most are taken by injection. The specific medications used, and their doses, depends on the underlying diagnosis and the egg supply of each woman. An individualized treatment plan will be developed.

Preparing the ovary to respond: In the hope of obtaining an appropriate number of growing eggs, certain medications can be used before or during the stimulation to affect the ovary’s response. These include birth control pills and other hormonal medications (such as estrogens, androgens, and growth hormone), as well as supplements such as coenzyme Q10.

Getting eggs to grow: Injections of follicle stimulating hormone (FSH) and luteinizing hormone (LH) or human chorionic gonadotropin (hCG) will stimulate egg growth. In some cases, the oral medications clomiphene citrate or letrozole are used.

Preventing premature ovulation: Gonadotropin releasing hormone (GnRH) analogs (leuprolide acetate, ganirelix, cetrorelix) are used to suppress premature ovulation.

Inducing maturation of eggs for fertilization: once the follicles are fully grown, a “trigger shot” of hCG or leuprolide acetate is given to mature the eggs.

Egg (Oocyte) Retrieval

* Eggs are removed from the ovary with a needle under ultrasound guidance.
* Anesthesia is typically given to make this more comfortable.
* Complications such as injury and infection are rare.

Oocyte retrieval is the removal of eggs from the ovary. This is done transvaginally with a needle guided by ultrasound. Very rarely, the ovaries cannot be reached through the vagina. In that case, the eggs might be removed by guiding the needle through the belly, or by inserting a viewing tube (laparoscope) through the belly button to reach the eggs. Anesthesia is generally used to reduce anxiety and discomfort.

Risks of egg retrieval:

*Infection*:  The incidence of infection (due to bacteria from the vagina being transferred to the ovaries or pelvis) after egg retrieval is very small (less than 0.1%).  If you do get an infection, you may be given antibiotics. Severe infections sometimes require surgery to remove infected tissue. Antibiotics may be used before or during the egg retrieval to reduce the chance of infection.

*Bleeding or Trauma*: A small amount of bleeding may occur as the needle passes through blood vessels. The risk of significant bleeding is small (<0.1%). Rarely, major bleeding or serious damage to nearby organs (intestines, bladder, ureters, ovaries) may occur and require treatment such as surgery and/or hospitalization for fluid or blood transfusions.

*Anesthesia:* The use of anesthesia while removing eggs can cause an allergic reaction or low blood pressure. It can also cause nausea or vomiting.

*Failure to obtain eggs:* Sometimes no eggs are found during the retrieval process. In other cases, the eggs are not mature, normal, or are of poor quality. These situations can prevent you from having a successful pregnancy.

In vitro fertilization and embryo culture

* Sperm and eggs are placed together in a petri dish.
* The dish is kept under special conditions to promote fertilization.
* The fluid in the dish (culture medium) helps the sperm fertilize the egg and helps embryos to grow. Each clinic may have its own blend of fluids in which to grow the embryos.

The fluid obtained from the ovaries is examined for eggs. The eggs can be frozen or inseminated with sperm. If inseminated, they are then “cultured” for a few days in laboratory incubators or a vaginal culture device.

Insemination of eggs can be done by placing sperm in the culture medium with the eggs, or directly injecting a single sperm into each egg, a process called Intracytoplasmic Sperm Injection (ICSI).    
  
Normal embryo development proceeds along the following schedule:

* *Day 1*: This is the day after the eggs were retrieved and inseminated. Eggs that have fertilized will still be a single cell but have 2 nuclei (so called “2PN”).
* *Day 2:* Normal embryos will divide into 2 to 4 cells.
* *Day 3:* Normal embryos will contain 4 to 8 cells (so called “cleavage stage”).
* *Day 5 or 6:* Normal embryos now have 100 cells or more and are called blastocysts. Blastocysts have a fluid-filled cavity, and a small cluster of cells called the inner cell mass.

It is important to understand that many eggs and embryos are abnormal. This means that some eggs will not fertilize, and some embryos will not divide at a normal rate. Some embryos may stop growing. Even embryos with normal development in the lab do not always produce a pregnancy. Some of these may be genetically abnormal.

The embryology laboratory has detailed procedures to ensure appropriate care of all eggs, sperm, and embryos, including proper identification and storage. Still, accidents have happened, including contamination of the culture system, equipment failure, human error, terrorist acts, and natural disasters such as hurricanes and floods, which may alter the outcome of an IVF cycle.

Certain decisions regarding this phase will need to be made beforehand, including:

* The manner of fertilization
  + The sperm can either be placed in the dish with the eggs to permit natural fertilization, or single sperm can be injected into each egg (“ICSI”). ICSI involves the direct injection of a single sperm into the interior of an egg using an extremely thin glass needle.  For men with poor quality sperm, ICSI increases the chance of fertilization. ICSI is also commonly done with frozen eggs, or eggs whose cloud of granulosa cells have been removed.
* The number of eggs to inseminate
  + If many mature eggs are available, you might choose to inseminate only some of them, and freeze the rest as eggs.
* What to do with extra eggs and/or embryos
  + Freezing of embryos is a common procedure.  Since multiple eggs are often produced during ovarian stimulation, on occasion there are more embryos available than are considered appropriate for transfer to the uterus. These embryos, if viable, can be frozen for future use. This saves the expense and inconvenience of stimulation to obtain additional eggs in the future.

Embryo transfer

* After a few days of culture/development, the best-developed embryos are chosen for transfer.
* The number of embryos transferred affects the chance of pregnancy and the risk of twins or other multiple pregnancies.
* The egg source’s age and the quality of the developing embryo(s) have the greatest effect on pregnancy outcome.
* Embryos are placed in the uterus using a thin tube under ultrasound guidance.
* Extra, normally developing embryos that are not transferred can be frozen for future use.

After a few days of development, the embryo transfer takes place, or the embryos are frozen for transfer later. One or more embryos are placed in the uterus using a thin tube called a catheter. Ultrasound may be used to help guide the catheter and confirm embryo placement.

Risks of embryo transfer include infection, no further development or damage to the embryo(s). Not all embryos become pregnancies, and not all pregnancies are normal or grow in the correct place (tubal pregnancies are possible). The number of embryos to transfer is an important decision. A woman’s age and the quality of the embryo affect both the chance for pregnancy as well as the chance for multiple embryos to implant. If multiple embryos implant, a multiple pregnancy (twins, triplets, or more) will result.  In some cases, an embryo can split into two (identical twins) after transfer. Before the transfer, it is critical to discuss with your doctor how many embryos to transfer.

Guidelines for the maximum number of embryos to transfer are given below (2021 update).

**RECOMMENDED LIMITS ON THE NUMBER OF EMBRYOS TO TRANSFER**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Age: | <35 | 35-37 | 38-40 | 41-42 | > 42 |
| Cleavage-stage embryos |  |  |  |  |  |
| * Normal # chromosomes | 1 | 1 | 1 | 1 | 1 |
| * From Egg Donor <35 | 1 | 1 | 1 | 1 | 1 |
| * Other favorable\* | 1 | 1 | ≤3 | ≤4 | Not known |
| * All others | ≤2 | ≤3 | ≤4 | ≤5 | Not known |
| Blastocyst-stage embryos |  |  |  |  |  |
| * Normal # chromosomes | 1 | 1 | 1 | 1 | 1 |
| * From Egg Donor <35 | 1 | 1 | 1 | 1 | 1 |
| * Other favorable\* | 1 | 1 | ≤2 | ≤3 | Not known |
| * All others | ≤2 | ≤2 | ≤3 | ≤3 | Not known |

\*Other favorable = any ONE of these criteria: Fresh cycle: expectation of 1 or more high-quality embryos available for freezing or previous live birth after an IVF cycle; Frozen embryo transfer cycle: availability of vitrified day-5 or day-6 blastocysts, Euploid embryos, 1st FET cycle, or previous live birth after an IVF cycle.

Hormonal support of the uterine lining

* For pregnancy to occur, the embryo(s) must attach to the lining of the uterus. This process is called implantation.
* The lining depends on two hormones – estradiol and progesterone – to permit implantation and sustain pregnancy.
* Endometrial preparation can be achieved in natural, stimulated, or medicated cycles.

The important hormones to support implantation are progesterone and estrogen. Normally, the ovary makes enough of both hormones to support pregnancy.   However, in recipient cycles, achieving this synchrony requires active management. When a natural cycle is used, the embryo transfer occurs about a week after ovulation. In some cases, ovarian stimulation is chosen to induce follicle growth; in this case embryo transfer again occurs about a week after ovulation. Programmed cycles involve providing estradiol and progesterone on a fixed schedule to prepare the uterus for pregnancy. In medicated cycles, estrogen and progesterone are supplied. Estrogen is given by mouth, patch, or vaginal suppository. Progesterone is given by the intramuscular or vaginal route.  These hormones are usually continued for several weeks to support the pregnancy. There are advantages and disadvantages to each of these approaches to preparing the uterus. Considerations such as feasibility, ease, scheduling, and risk are weighed. There are certain differences in obstetric and neonatal outcomes to consider.

Additional Elements

Intracytoplasmic Sperm Injection (ICSI)

* In some cases, especially when sperm are of poor quality, fertilization will not happen naturally. Injecting a sperm into each egg (ICSI, or intracytoplasmic sperm injection) can help fertilization occur.
* ICSI does not guarantee normal fertilization.
* ICSI will not improve any defects in the eggs.

ICSI involves the direct injection of a single sperm into the interior of an egg using an extremely thin glass needle. This lets the sperm enter the egg without having to break through the shell around the egg (the zona pellucida).

ICSI is a good choice when the sperm count, movement, or quality is poor. Live birth rates are very close to those of IVF for men with normal sperm counts.

However, ICSI may be associated with a slightly higher risk of birth defects. It is hard to know if the increased risk is due to the ICSI procedure itself or to defects already present in the sperm. The risk of birth defects after ICSI is still quite small (4.2% compared with 3% in children conceived naturally .

Children conceived by ICSI have slightly more problems with their sex chromosomes (the X and Y chromosomes) than children conceived by IVF alone, but only by a very small margin (0.8% to 1.0% for ICSI pregnancies compared to 0.2% for IVF pregnancies). The reason for the difference is not clear. It may be caused by the ICSI procedure itself, or by the chromosomes carried by the father. Men with sperm problems such as very low count and low motility are more likely to have genetic abnormalities.

Assisted Hatching

* Assisted hatching involves making a small hole in the outer shell (zona pellucida) that surrounds the embryo.
* Hatching may make it easier for embryos to be released from the shell and implant in the uterus.

The cells that make up the early embryo are enclosed by a shell called the zona pellucida.  Normally, as the embryo grows, this shell breaks open and releases the embryo. “Assisted hatching” makes it easier for the embryo to escape the shell. This is done in the embryology laboratory by making a small hole in the shell with a needle or a laser. Assisted hatching may have some risks, including more identical twinning and (rarely) damage to the embryo.

Preimplantation Genetic Testing (PGT)

* Preimplantation genetic testing of embryos currently requires removal of cells from the embryo (embryo biopsy).
* This test is most often done on Day 5 or Day 6 of embryo development, but it may be done sooner in some circumstances.
* The cells removed from the embryo may be sent to an off-site lab for the testing, while embryos remain in storage at the clinic.
* In most cases, the tested embryos will need to be frozen while the test is being run.
* Test results can be incorrect. Genetic testing does not guarantee the birth of a perfectly healthy baby.
* Some clinics automatically discard embryos identified as abnormal. This should be discussed with your clinic before the testing is done.

There are several reasons that some Intended Parents choose to do PGT. Current reasons include:

* determining whether the embryo has the correct number of chromosomes (so called “aneuploidy”) (“PGT-A”).
* determining whether the embryo has a structural rearrangement /translocation of its chromosomal material (“PGT-SR”).
* determining whether the embryo has a specific disease-causing mutation (“PGT-M”)
* determining the genetic sex of the embryo.

PGT does not guarantee that a pregnancy will occur, even if embryo testing is normal. Factors other than the genes or chromosomes also influence the chance for pregnancy.

Screening the embryo’s chromosomes, or testing for one specific genetic disease, does not guarantee that the embryo will be healthy and free of other disorders. For example, some common disorders that cannot be checked with PGT are autism and diabetes. Some birth defects can also occur even if chromosome screening is normal. An example of this would be a cleft lip or palate (failure of the lip and upper mouth to join properly).

Risks of embryo biopsy

1. *Embryo damage.* There is a small risk of damage to the embryo. This may result in no pregnancy when one would have occurred if not for the biopsy procedure.
2. *No result.* The test may not give a result in up to 5% of cases. Sometimes, there is not enough material retrieved to run the test. It may be possible to repeat the biopsy and try again to test the embryo.
3. *Mixed results or diagnosis, such as mosaicism*. Test results can suggest that 2 different populations of cells exist in the embryo (normal cells and abnormal cells together). There is currently no evidence to determine which, if any, embryos designated as mosaic may have a chance to result in a successful, healthy pregnancy. Some clinics will not transfer mosaic embryos. This should be discussed with your clinic staff. Lower implantation rates and higher miscarriage rates have been reported with transfer of mosaic embryos; however apparently several healthy live births have also been reported.
4. *Misdiagnosis.* The test may give the wrong result, and say that a normal embryo is actually abnormal, or that an abnormal embryo is actually normal. The accuracy of the testing is determined by the off-site lab. Most testing is very accurate, so the chance of a misdiagnosis is low. Furthermore, since not all embryos are made up of cells with identical genetics (“mosaicism”), it is possible that accurate test results do not reflect the genetics of the entire embryo. Consequently, the current recommendation is to confirm the result in early pregnancy.

*Note that depending on Clinic policy, embryo selection based on the sex of the embryo, and/or the transfer of genetically abnormal embryos, may not be permitted. Please review your Clinic’s policies.*

   Embryo Freezing

* Freezing of eggs or embryos provides an additional chance for pregnancy in the future.
* Frozen eggs and embryos do not always survive the freezing and thawing process
* Ethical and legal questions can arise when couples separate or divorce. It is vital to agree on what will be done with remaining eggs or embryos in those cases.

There are many reasons eggs and/or embryos may be frozen: they may be surplus, they may be undergoing genetic testing, the uterine environment for a fresh transfer is thought to be compromised, or the risk of ovarian hyperstimulation syndrome (OHSS) may be high. Some women may wish to freeze their eggs instead of embryos because they are not ready to conceive with their current partner, because they are planning to have therapy such as cancer treatment that could damage their eggs, or, regardless of their current circumstances, because they want to retain their reproductive autonomy. While freezing helps extend fertility, it is not without some risk and does not guarantee that the frozen eggs or embryo will be available for later use.

*Risks of freezing:*

Not all eggs or embryos will be successfully frozen.  The process of freezing, storage, and thawing can damage eggs or embryos.  This means that not all eggs or embryos may be available for further treatment.

There is a very small potential risk that gametes or embryos that are frozen may not be properly labeled or transferred to the individual(s) who stored them. This can arise from human error in fertilizing eggs or human or mechanical errors in labeling and storing eggs, sperm or embryos. While every SART clinic and embryology lab has protocols designed to avoid such errors through reasonable efforts to properly identify, label, store, thaw, and transfer reproductive tissue, errors in these steps are possible and patients understand and accept the risks inherent in such steps.

Studies of animals and humans indicate that children born from frozen embryo cycles do not have any greater chance of birth defects than children born after fresh embryo transfers.  However, until very large numbers of children have been born from frozen embryos, it is not possible to be absolutely certain that there are no increased risks.

*If you choose to freeze eggs or embryos, you MUST complete the Disposition of Embryos (or Eggs) Agreement before freezing. This statement may need to be notarized. The statement explains the choices you have for disposing of the eggs or embryos in a variety of situations that may arise. You can submit a new statement later if you change your mind about your choices. For frozen embryos, any change requires that both parties — you and your partner-- agree in writing to the change.*

Risks to the Woman

Overall risk to the female undergoing ovarian stimulation, oocyte retrieval, and embryo transfer is very low. In fact, the most frequent complication is ovarian hyperstimulation syndrome, OHSS, which occurs in <1.5% of cycles. OHSS is more common in women with high ovarian reserve such as women with polycystic ovary syndrome who have a high number of eggs retrieved. Other complications such as hemorrhage, transfusion, infection, or hospitalization are even more rare, <0.1% of cycles.

Risk of Medications

Common side effects of medications used for ovarian stimulation include hot flashes, vaginal dryness, nausea, headaches, and muscle aches. Some women may retain fluid (bloating) or have moodiness. Any injection can cause bruising, redness, swelling, or pain at the injection site. In rare cases, there may be a severe allergic reaction, infection at injection sites, blood clots or stroke. Reactions may vary based upon the type woman’s underlying diagnosis/medical status and medication dosages.

Infection

Although low, it is possible to see infection at medication injection sites, or after an egg retrieval or embryos transfer. This possibility is reduced by using good injection technique and taking prescribed antibiotics.

Ovarian Hyperstimulation Syndrome (OHSS)

Stimulating the ovaries can lead to OHSS, which is uncomfortable at a minimum and can lead to nausea, vomiting, trouble breathing, pain and a buildup of fluid in the belly or abdomen/stomach. Mild to moderate cases are often managed at home with medication and fluid monitoring and resolve over several days. Severe cases are rare (less than 1.5% of IVF cycles)] but can be associated with blood clots and damage to the kidneys or liver and may even lead to kidney failure or death particularly if not managed by a fertility provider. These cases require hospitalization.

Measures to prevent OHSS include delaying embryo transfer, avoidance of hCG to trigger egg maturation, and taking the medication cabergoline.

Cancer

Women with infertility are known to be at increased risk of certain cancers, so whether IVF increases the risk further is difficult to assess. In current studies that take into consideration the increased risk of cancer due to nulliparity (never having been pregnant) there does not seem to be an increased risk of cancer due to the fertility drugs alone.

Risks of Pregnancy

Getting pregnant through IVF comes with certain risks. This is partly because women using IVF are often older than those who might get pregnant on their own. In addition, the cause of the infertility itself may increase certain risks. The table below indicates risk in those doing IVF relative to other infertile women. In 2019, 7% of IVF pregnancies were twin and <1% were triplets or greater).

Risks of Pregnancy with IVF

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Singleton Pregnancies | | Twin Pregnancies | |
|  | Incidence in IVF Pregnancies (%) | Incidence among infertile women | Incidence in IVF Pregnancies (%) | Incidence among infertile women |
| Gestational diabetes | 8.2% | No difference | 10.7% | No difference |
| Pregnancy-induced hypertension | 12.6% | No difference | 25.5% | No difference |
| Placental complications | 5.2% | 2.6% | 4.9% | No difference |
| Primary cesarean delivery | 32.2% | 29.3% | 65.4% | 60.6% |
| Low birthweight (<5.5 pounds) | 7.7% | 6.4% | 50.4% | No difference |
| Preterm birth (<37 weeks gestation | 10.3% | 8.2% | 53.8% | No difference |

Multiple pregnancies in general have an increased risk of pregnancy problems such as early delivery, pre-eclampsia (high blood pressure and protein in the urine), excess bleeding with delivery, and diabetes during pregnancy.

In IVF, embryos are transferred directly into the uterus. Still, tubal, cervical, or abdominal pregnancies can sometimes occur. These abnormal pregnancies may need to be treated with medication or surgery. Abnormal pregnancies within the uterus can also occur, which may also require medical or surgical intervention.

Risks to the Baby

* IVF babies may be at a slightly higher risk for birth defects and genetic defects.
* IVF has a greater chance of multiple pregnancy, even when only one embryo is transferred.
* A multiple pregnancy is the greatest risk to your baby when using IVF.

The first IVF baby was born in 1978. Since then, more than 10 million children around the world have been born through IVF.  Studies have shown that these children are quite healthy overall.

Birth Defects

The risk of all birth defects through natural or spontaneous conception is about 3-5%. In IVF babies, the risk for any birth defect is about 5-6%. There may be, specifically, an increased risk of cardiac (heart) defects. Most of the increased risk with IVF seems to be due to the pre-existing infertility in couples using IVF and older maternal age.

There are a few other potential increased risks for babies born through IVF:

*Imprinting Disorders*. These are very rare disorders caused by certain genes from the mother or the father not being expressed. An example is Beckwith-Wiedemann Syndrome, which is more common in children conceived with IVF. These disorders are extremely rare (1 out of 15,000 people). Children from IVF treatment have a small increased risk of 0.01%.

*Childhood cancers*. There does not appear to be a higher risk of most cancers in children born from IVF, but there may be a higher risk of hepatic (liver) cancer. These are very rare in children.

*Infant development.* Most studies of long-term developmental outcomes for children have been reassuring so far. However, these studies are hard to do, and they have some limitations. There may be an increased risk of cerebral palsy however this risk is mostly from prematurity and low birth weight resulting from multiple pregnancy. Some studies show an increased risk of autism associated with ICSI, but others do not.

Risks of a Multiple Pregnancy

It is riskier for a baby to be a twin or triplet than a single pregnancy. Fortunately, fewer than one in ten IVF pregnancies are multiple, and that rate is declining due to lowering the number of embryos transferred into the uterus.

Early delivery accounts for most of the extra problems associated with babies from multiple pregnancies. IVF twins deliver an average of three weeks earlier than IVF single babies, and they weigh about 2 pounds less than IVF single babies.  Triplet (and greater) pregnancies deliver before 32 weeks (7 months) in almost half of cases. Early delivery can increase the risk of cerebral palsy, retinopathy of prematurity (eye problems that result from early delivery), and chronic lung disease. Multiple pregnancies also have increased risk of growth problems in the uterus, so the babies are born a low weight.

Multiple fetuses that share the same placenta, such as most identical twins, have additional risks, such as birth defects. Twin-to-twin transfusion syndrome, where the circulation is not equal between the fetuses, may occur in up to 20% of twins who share a placenta. This can increase the risk of fetal death.

Lastly, there is an increased risk of stillbirth with multiple pregnancies. The risk of stillbirth for a singleton pregnancy is 0.54%. The risk with twins is higher at 2.3% and with triplets 5.3%. The death of one or more fetuses in a multiple pregnancy (“vanishing twin”) can happen in the pregnancy and can happen in up to 36% % of twin pregnancies. This can affect the health of the surviving fetus.

# Psychosocial Effects of Infertility Treatment

Finding out that you or your partner is infertile or have a lower fertility can be very painful. Infertility and its treatment can affect your emotions, your health, your finances, and your social life. Treatment, particularly IVF, is time-consuming and may strain your personal relationships and your religious or ethical beliefs. During treatment, you may feel anxious, helpless, depressed, or all alone. You may go through highs and lows. In some cases, you may want to seek the help of a mental health expert to help you through the pressures treatment presents. Your clinic can provide resources to professional in your area.

# Reporting Outcomes

In 1992, the Fertility Clinic Success Rate and Certification Act was passed.  This law requires the Centers for Disease Control and Prevention (CDC) to gather information about IVF cycles and pregnancy outcomes in the U.S. each year.  This information is used to calculate success rates which are reported each year.

We (the Clinic) will report the required information from your IVF procedure to the CDC.  Since our Clinic is a member of the Society of Assisted Reproductive Technologies (SART) of the American Society for Reproductive Medicine (ASRM), it will also be reported to SART.  Information reported to SART about your cycle may be used for research or quality assessment according to HIPAA guidelines; your name will never be connected to your cycle information in any research that is published by ASRM or SART.

# Informed Consent

You acknowledge that you have read this entire In Vitro Fertilization Information and Consent document and have had the opportunity to ask your physician any questions you may have about participation. Your consent to IVF is purely voluntary. You acknowledge that your doctor has provided you with alternatives to IVF for procreation and family building, including other medical treatment or non-treatment options. You have specifically declined to accept these options.

You also confirm that you have reviewed this In Vitro Fertilization Information and Consent document with your physician or designated Clinic staff and have had an opportunity to have your questions answered. You also acknowledge that you have been advised of the risks and benefits of undergoing the procedures involved and the possible alternatives available to me.

I (we) acknowledge that I have read and understood the information provided above regarding the IVF process and its risks and agree to go forward with this treatment as my signature below testifies.

X

Intended Parent A Signature Date

Intended Parent A Name Date of Birth

Notary Public (if signed out of office)

Sworn and subscribed before me on this \_\_\_\_\_ day of \_\_\_\_\_\_\_\_\_, \_\_\_\_\_\_\_\_\_\_.

Notary Signature Date

------------------------------------------------------------------------------------------------------------------

X

Intended Parent B Signature Date

Intended Parent B Name Date of Birth

Notary Public (if signed out of office)

Sworn and subscribed before me on this \_\_\_\_\_ day of \_\_\_\_\_\_\_\_\_, \_\_\_\_\_\_\_\_\_\_.

Notary Signature Date

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If signed in the office:

Statement by Witness (must be employee of Clinic and at least 18 years of age)

I declare that the person(s) who signed this document is personally known to me and appears to be of sound mind and acting of their own free will. They signed (or asked another to sign for him or her) this document in my presence.

Witness Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Witness Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# Additional Information

General IVF information:

From the American Society for Reproductive Medicine: [www.reproductivefacts.org](about:blank)

From the Society for Assisted Reproductive Technologies: [www.sart.org/](about:blank)

* + - * Patient predictor: [https://w3.abdn.ac.uk/clsm/SARTIVF/home/toolintro](about:blank)
      * IVF Infographics: [https://www.sart.org/patients/history-of-ivf/](about:blank)

From the Centers for Disease Control: [www.cdc.gov/art/](about:blank)

From RESOLVE: [https://resolve.org](about:blank)