Recipients of Donor Eggs

Process, Risks, Consent

Date: _____

Partner #1 **Last Name**: _____ **First Name**: _____

ID#_____ Gender – M / F (Circle One)

Partner #2 **Last Name**: _____ **First Name**: _____

ID #_____ Gender – M / F (Circle One)

Donor Egg (DE) therapy treats infertility due to egg problems or certain genetic issues. The goal of DE is to become pregnant using eggs from a donor.

The donor can be known or non-identity release, and the eggs can be fresh or from an Egg Bank.

Treatment Type: ☐ Non-identity release donor
☐ Directed (ID: _____)

☐ Fresh ☐ Egg Bank

Steps in the Process

First an egg donor needs to be identified and her eggs retrieved. This involves screening possible donors for their health, then getting some of their eggs.

Screening of Egg Donor

The medical, psychological, genetic and family history of possible egg donors are evaluated to make sure they are healthy. No screening or testing regimen is perfect, so it is possible for children with major congenital malformations (birth defects) or health problems to occur despite appropriate screening. All donors are also tested for infectious diseases including HIV (the virus responsible for AIDS), syphilis, and hepatitis (types B and C). Even with this screening, it is possible that an infectious disease could be transmitted to a child conceived with the donated eggs or to the woman who will carry the pregnancy.

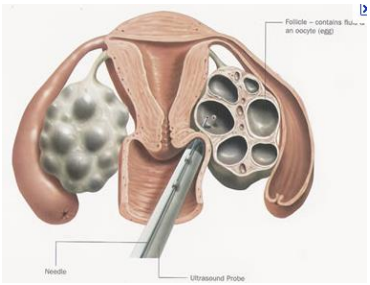
Ovarian Stimulation of the Donor

Medications are used to stimulate the ovary in hopes of growing several eggs at once. Monitoring of the donor's ovarian response by ultrasound is important.

This process does not use up the donor's eggs. The eggs that grow were already "linked" to cycle and would have died anyway.

Egg Retrieval from a Donor

A transvaginal ultrasound probe is used to see the ovaries and the egg-containing follicles within the ovaries. A long needle is guided into each follicle and the fluid is drained out. The fluid contains the egg.



Using the Donated Eggs

Recipients select the donor. All donors must pass screening before any of their eggs can be used. Once you have selected the donor, a schedule can be developed for the embryo transfer. If the donor eggs are already in an Egg Bank, the transfer can often occur within a few weeks. If the donor needs to undergo ovarian stimulation to produce the eggs, additional time will be needed, and synchronization of the donor's cycle and the recipient's cycle is usually done.

In Vitro Fertilization

The eggs, whether fresh or thawed, are kept in conditions that support their needs and growth. The eggs are placed in small dishes or tubes containing "culture medium," which is special fluid developed to support development of the embryos. The fluid is made to resemble the conditions in the Fallopian tube and uterus. The dishes are then placed into incubators, which keep the temperature, humidity,

gas and light at just the right levels.

Sperm are then placed in the culture medium with the eggs, or individual sperm are injected into each mature egg in a technique called Intracytoplasmic Sperm Injection (ICSI) (see below). The eggs are then returned to the incubator, where they remain to develop. Their development is checked over the next few days.

Embryo development usually proceeds along the following schedule:

- *Day 1*: The fertilized egg is still a single cell with 2 nuclei, and is called a "2PN" or zygote.
- Day 2: Normal embryos will divide into 2 to 4 cells.
- Day 3: Normally developing embryos will continue to divide and contain 4 to 8 cells.
- Day 4: The cells of the embryo begin to merge to form a solid ball of cells called a morula (named because it looks like a mulberry).
- Day 5: Normal embryos now have 100 cells or more, and are called blastocysts. It has an inner fluid-filled cavity and a small cluster of cells on the inside called the inner cell mass.

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

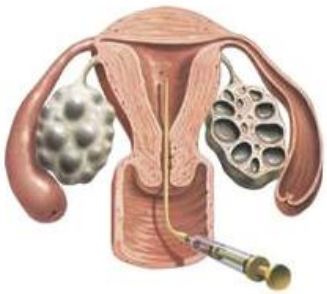
- The manner of fertilization
  - The sperm can either be placed in the dish with the eggs to permit natural fertilization, or single sperm can be injected into each egg ("ICSI"). ICSI involves the direct injection of a single sperm into the interior of an egg using an extremely thin glass needle. For men with few or 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 (or "cryopreservation") 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 into Recipient or Carrier

- **After a few days of development, the best embryo(s) are selected for transfer.**
- **The number of embryos transferred affects the pregnancy rate and the risk for twins and other multiple pregnancies.**
- **Embryos are placed in the uterine cavity using a thin tube.**
- **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 on. One or more embryos are placed in the uterine cavity using a thin tube (catheter). Ultrasound may be used to help guide the catheter. It can also confirm placement through the cervix and into the uterine cavity.

The number of embryos to transfer is an important decision. Age and embryo quality 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, and 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. If you donor is under age 35 and the best embryo looks normal, then in most cases only one embryo should be transferred.

Hormonal Support

- **For a 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.**

The important hormones to support implantation are progesterone and estrogen. Normally, the ovary makes sufficient amounts of both hormones to support pregnancy. However, in recipient cycles, the ovaries are quiet, so they need to be given as medicines. Progesterone is given by the intramuscular or vaginal route. Estradiol is given by the oral, vaginal, transdermal or intramuscular route. These hormones are usually continued for several weeks to support the pregnancy.

Additional Elements appropriate in some cases:

Intracytoplasmic Sperm Injection (ICSI)

- **In some cases, fertilization will not happen when eggs and sperm are placed together in a lab dish. Injecting a sperm into each egg (ICSI, or intracytoplasmic sperm injection) can help fertilization occur.**
- **ICSI does not guarantee normal fertilization.**
- **There may be an increased risk of genetic problems in children born from ICSI.**
- **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*) on its own. For it to work, the sperm must be healthy, and the egg must be mature.

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.

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 in the sperm. The risk of birth defects after ICSI is still quite small (4.2% compared with 3% in children conceived naturally). Experts are still debating the impact of ICSI on the mental and physical development of children. Most recent studies have not detected any differences in the development of children born after ICSI, regular IVF, or natural conception.

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 father. Men with sperm problems such as very low count and low motility are more likely to have genetic abnormalities. They often produce sperm with abnormal chromosomes, especially with abnormal sex chromosomes (X and Y). If sperm with abnormal chromosomes produce pregnancies, the pregnancies will likely carry the same defects. Translocations (a re-arrangement of chromosomes that can cause miscarriage or birth defects) may be more common after ICSI.

Some men with extremely low sperm counts or no sperm have small deletions on their Y chromosomes. In some of these cases, sperm can be obtained to fertilize eggs with ICSI. Any sperm containing a Y chromosome microdeletion will pass on the deletion to any male child. These male children will also carry the microdeletion and may be infertile. A Y chromosome microdeletion can often, but not always, be detected by a blood test. This is because the chromosomes in the sperm may not always be the same as those seen when tested in the blood.

Some men are infertile because the tubes connecting the testes to the penis did not form the right way (congenital bilateral absence of the vas deferens [CBAVD]). These men can still father children, but sperm must be taken directly from the testicles or the tubes next to them. This sperm is then used in ICSI. These men have a mild form of cystic fibrosis (CF), which can be passed on to their children. Men with CBAVD and their partners should be tested for CF gene mutations before treatment. However, some CF mutations may not be detected by current tests, so that some parents who test negative for CF mutations can still have children affected by CF.

Preimplantation Genetic Testing (PGT)

- **Preimplantation genetic testing of embryos requires removal of one or more 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 (cryopreserved) while the test is being run.**
- **Test results can be incorrect.**

There are several reasons that some patients choose to do PGT. Current reasons include:
- determining whether the embryo has the incorrect number of chromosomes ("PGT-A").
- determining whether the embryo has a structural rearrangement of its chromosomal material ("PGT-SR").
- determining whether the embryo has a specific disease-causing mutation ("PGT-M")
- determining the gender of the embryo.

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

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).

It is always a possibility that PGT will show that there are NO normal embryos available to transfer.

There are risks to embryo biopsy:

- Damage. There is a small risk of damage to the embryo. This may result in no embryos to transfer.
- No result. The test may not give a result. Sometimes, there is not enough genetic material retrieved to run the test. It may be possible to repeat the biopsy and try again to test the embryo.

- 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 testing is determined by the off-site lab. Most testing is very accurate, so the chance of misdiagnosis is low. However, since not all embryos are made up of cells with identical genetics ("mosaicism"), it is possible that an accurate test result does not reflect the genetics of the entire embryo. Consequently, the current recommendation is to confirm the result in early pregnancy.

Assisted Hatching

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

The cells that make up the early embryo are coated with a membrane (shell) called the zona pellucida. Normally, as the embryo grows, this shell melts away. This lets the embryo escape or "hatch" from the shell. Only after hatching can the embryo implant in the uterus to form a pregnancy.

Assisted hatching makes it easier for the embryo to escape the shell. This is done on the lab, by making a small hole in the shell with a needle, a laser, or with chemicals. The procedure is usually done on the day of transfer, before loading the embryos into the transfer catheter.

Some programs use assisted hatching because of the belief that it improves implantation and birth rates. There is no absolute evidence of this, however. In most cases, assisted hatching is believed to be helpful in women who are over 38 years old when their eggs are harvested, or if they have failed to get pregnant in a previous IVF cycle. It can also be done when the shell around the embryo is extra thick. The thickness of the shell is checked on all embryos before embryo transfer.

Assisted hatching does have some risks. Very rarely, the embryo can be damaged, lose cells, or even be destroyed. There is also a higher chance of having identical twins, which is a more risky pregnancy. There may also be other risks not yet known.

Cryopreservation

- **Freezing of eggs and embryos provides other chances for pregnancy in the future.**
- **Frozen eggs and embryos do not always survive the process of freezing and thawing.**
- **Freezing of eggs before fertilization does not work as well as freezing of embryos.**
- **Ethical and legal questions can arise when couples separate or divorce. It is vital to agree on what will be done with remaining embryos in those cases.**
- **A person or couple with frozen eggs or embryos MUST be in touch with the Clinic once a year.**
- **There are usually yearly fees that go along with keeping embryos or eggs frozen.**

Sometimes there are normally developing embryos left after embryo transfer. Extra normal-appearing embryos can be frozen for future use. In some cases, it may be planned for all embryos from an IVF cycle to be frozen (for example, when PGS is used). On the other hand, some women may wish to freeze their eggs because they are not ready to conceive now, or because they will have treatment such as cancer treatment that may destroy their eggs.

Benefits of freezing:

- Saves you from going through ovarian stimulation again if you need eggs or embryos in the future.

- Lets you transfer fewer embryos in the fresh cycle, and keep the others for a frozen cycle. This can reduce the risk of becoming pregnant with more fetuses.
- Lets you freeze all embryos in the fresh cycle to prevent over-stimulation of the ovaries.
- Lets you freeze embryos while waiting for test results from PGS or PGD.
- Protects you if your future fertility is at risk because of surgery or other treatments such as cancer therapy.

There are different ways to freeze embryos. The most common are "slow" freezing and "rapid" freezing (called *vitrification*). You should know that embryos do not always survive the freezing and thawing process. There is always a risk that no embryos will survive. If this happens, the transfer will have to be cancelled. 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 Eggs or Disposition of Embryos statement before freezing*. This statement must also 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. Be sure to let us now if you change your address. You must also pay storage fees as they come due.*

Risks

Risks to Egg Donor

Transvaginal Egg Retrieval

Infection*:* Bacteria from the vagina may be transferred into the stomach area or ovaries by the needle. This can cause an infection of nearby organs. The incidence of infection after egg retrieval is very small (less than 0.1%). If an infection occurs, antibiotics are given. Severe infections sometimes require surgery to remove infected tissue. Infections can reduce the chance of getting pregnant in the future. Antibiotics may be used before the egg retrieval to help reduce the chance of infection. Still, there is no way to remove the risk completely.

Bleeding*:* The needle passes through the vaginal wall and into the ovary to obtain the eggs. Both of these structures contain blood vessels. There are also other blood vessels nearby. This means that small amounts of blood may be lost while removing the eggs. The risk of major bleeding is small (< 0.1%). Major bleeding may require surgery to stop, and could result in the removal of an ovary. Only rarely is a blood transfusion needed. If bleeding occurs and is not noticed (also rare), it can lead to death.

Trauma*:* Even with ultrasound guidance, nearby organs can be damaged. This includes damage to the intestines, appendix, bladder, ureters, and ovary. In some cases, a damaged organ may need to be fixed or removed through surgery. Still, the risk of damage during egg retrieval is very low.

Anesthesia*:* The use of anesthesia while removing eggs can cause an allergic reaction or low blood pressure. It can also cause nausea or vomiting. In rare cases, use of anesthesia has resulted in death.

***Failure*:** Sometimes no eggs are found during the retrieval process. In other cases, the eggs are not normal, or are of poor quality

Ovarian Hyperstimulation Syndrome (OHSS)

OHSS is an occasional outcome of stimulating the ovaries. Signs of OHSS include increased ovarian size, nausea and vomiting, and buildup of fluid in the stomach. Difficulty breathing can happen. In some cases, OHSS increases the level of red blood cells, and causes kidney and liver problems. In the most severe cases, it can cause blood clots, kidney failure, or death. All these complications occur very rarely (in less than 1 in 1,000 cycles).

Cancer

There is some concern that using fertility drugs can cause breast, ovarian, or uterine cancer. These cancers are more common in women with infertility, so it is difficult to know whether the reason for the cancer is infertility or use of the drugs. In current studies that take into consideration the increased risk of cancer due to infertility, there does not seem to be an increased risk of cancer due to the fertility drugs alone. More studies need be done to confirm whether there is an association of cancer with use of fertility drugs.

Risks to Egg Recipient

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 be to blame. There may be other risks linked to IVF that are not known at this time. Please see the table below for certain known risks.

Risks of Pregnancy with IVF

	Singleton Pregnancies			**Twin Pregnancies**		
	Incidence in IVF Pregnancies (%)	Risk compared to other infertile women	Risk compared to fertile women	Incidence in IVF Pregnancies (%)	Risk compared to other infertile women	Risk compared to fertile women
Gestational diabetes	8.2%	No difference	41% higher	10.7%	No difference	23% higher
Pregnancy-induced hypertension	12.6%	No difference	No difference	25.5%	No difference	15% higher
Placental complications	5.2%	95% higher	281% higher	4.9%	No difference	83% higher
Primary cesarean delivery	32.2%	10% higher	20% higher	65.4%	8% higher	17% higher
Low birthweight (<5.5 pounds)	7.7%	21% higher	65% higher	50.4%	No difference	No difference
Preterm birth (<37 weeks gestation	10.3%	26% higher	70% higher	53.8%	No difference	7% higher

About 25% of IVF pregnancies are multiple pregnancies (twins, triplets, or greater) in 2015, of which less than 1% are triplets or more. Identical twins occur in less than 5% of all IVF pregnancies. Identical twins may happen more often after blastocyst (Day 5 or 6) transfers. Multiple pregnancies in general have an increased risk of pregnancy problems. In addition to early delivery, problems include pre-eclampsia (high blood pressure and protein in the urine), excess bleeding with delivery, and diabetes of pregnancy (gestational diabetes). Problems with the placenta (afterbirth) are also more common. Other problems more common with multiple pregnancy include gall bladder problems, skin problems, and the need for extra weight gain.

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.

Age-related risk to recipient / carrier

Certain risks of pregnancy increase with age. Most common are high blood pressure, diabetes, bleeding while pregnant, and growth problems for the baby. Above 44 years of age, it is prudent to have a consultation and full medical evaluation before becoming pregnant. This may involve both an internist and a high-risk obstetrician.

Risks to Your 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.**

Overall Risks

The first IVF baby was born in 1978. Since then, more than 5 million children around the world have been born through IVF. Studies have shown that these children are quite healthy. In fact, some experts believe having a child through IVF is now just as safe as having a child naturally. Still, one must be careful when making this claim. Infertile couples do not have normal reproductive function. This means that a baby they have through IVF may have more health problems than a baby conceived naturally.

IVF single babies are often born about 2 days earlier than naturally conceived babies. They are about 5% more likely to weigh less than 5 pounds, 8 ounces (low birthweight) than a naturally conceived single baby.

IVF twins are not born earlier or later than naturally conceived twins.

The risks of freezing have been checked in animal tests over several generations. Human data has also been checked. There is no proof that children born from frozen and thawed embryos or frozen and thawed eggs have any more health problems than those born from fresh embryos. Still, it is hard to know for sure if the rate of health problems is the same as the normal rate.

Birth Defects

The risk of birth defects through normal birth is about 4.4 percent, and it is about 3% for severe birth defects. In IVF babies, the risk for any birth defect is about 5.3%, while the risk for a severe birth defect is about 3.7%. Most of the increased risk with IVF seems to be due to older mothers and to having infertility. No higher risk is seen in frozen embryo or donor egg cycles.

Imprinting Disorders. These are rare disorders caused by whether the genes from the mother or the genes from the father are working. Studies do not agree on whether these disorders are associated with IVF. Even if they are, these disorders are extremely rare (1 out of 15,000 people).

Childhood cancers. Most studies do not suggest any extra risk, except for retinoblastoma (a cancer behind the eye). One study did report an increased risk after IVF treatment, but further studies did not find an increased risk.

Infant development. Most studies of long-term developmental outcomes have been reassuring so far. Most children are doing well. However, these studies are hard to do, and they have some limitations. A more recent study using better methods shows an extra risk of cerebral palsy and developmental delay). However, this arose mostly from prematurity and low birth weight that was a result of multiple pregnancy.

Risks to Offspring of a Multiple Pregnancy

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. Fetal growth problems and unequal growth among the fetuses can also result in perinatal disease and death before or shortly after delivery.

Multiple fetuses that share the same placenta, such as most identical twins, have additional risks. 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. Twins sharing the same placenta have a higher frequency of birth defects compared to twins with two placentas. Death of one fetus in a twin pregnancy after the first trimester is more common with a shared placenta; this may cause harm to the remaining fetus.

Other problems babies can face include cerebral palsy, retinopathy of prematurity (eye problems that result from early delivery), and chronic lung disease. No one knows how much multiple pregnancies affect neurological or behavioral development, even when none of the other problems occur.

Fetal death rates for single pregnancies are 4.3 per 1,000. For twins, that number is higher at 15.5 per 1,000; and for triplets, the fetal death rate is 21 per 1,000. The death of one or more fetuses in a multiple pregnancy ("vanishing twin") is more common in the first trimester and may be happen in up to 25% of IVF pregnancies. Loss of a fetus in the first trimester does not usually affect the surviving fetus.

The Option of Multifetal Pregnancy Reduction (Selective Reduction): The more fetuses there are in the uterus, the greater the chance of a problem. Patients with twins or more have 3 choices:

- Continue on with the pregnancy (with all the risks that have already been stated),
- End the pregnancy.
- Reduce the number of fetuses (terminate one or more of the fetuses) to lower the health risks to mother and child.

Reducing the number of fetuses lowers the risk of early delivery. This can be a difficult decision to make. The main danger is losing the entire pregnancy. The odds of losing the entire pregnancy are about 1 in 100 (1%). The odds of losing the entire pregnancy are greater if there are more than 3 fetuses present before the procedure is done.

Limits to the Success of the Process

There are a number of reasons IVF using donated eggs may be unsuccessful:

- Inadequate egg development in the egg donor may result in cancellation of the cycle prior to egg retrieval.

- The egg donor may respond too vigorously to the medications and be at risk of ovarian hyperstimulation syndrome (OHSS) and this may necessitate cancellation of the cycle prior to egg retrieval.
- Ovulation may occur spontaneously before the donor eggs can be retrieved.
- The egg donor may not be able to complete the cycle for medical, personal or logistical reasons and may withdraw from the treatment cycle before the egg retrieval.
- In rare cases, no donor eggs may be retrieved.
- The donor eggs may not be normal.
- A fresh semen sample may not be able to be produced the day of the procedure; a frozen specimen (if previously provided) will then be utilized, however, this may result in fewer eggs being fertilized.
- The frozen sample of sperm or tissue may be unusable or non-viable.
- Fertilization may not occur, or may occur abnormally, e.g. an egg may be fertilized by more than one sperm and could develop abnormally. Fertilization may not occur or abnormal fertilization may occur, even with the use of intracytoplasmic sperm injection. Such embryos will not be transferred.
- Intracytoplasmic sperm injection may result in damage, destruction or loss of one or more eggs (oocytes) or sperm.
- Cleavage or cell division of fertilized eggs may not occur.
- The embryos may not develop normally.
- Selective assisted hatching may lead to damage or loss of one or more embryos.
- The embryo transfer may be difficult or may not be possible.
- An anonymous egg donor's infectious disease testing results (performed within 30 days of the egg retrieval) may be unavailable making it necessary to freeze all the eggs or embryos for use at a later time.
- An anonymous egg donor's infectious disease testing results (performed within 30 days of the egg retrieval) may be positive making it necessary to discard the eggs or embryos. If the eggs or embryos need to be discarded (no embryo transfer takes place), we (I) understand that we (I) are financially responsible for all charges resulting from our egg donation cycle, including fees for the donor, recipient and partner, up to and including the day the eggs or embryos are discarded.
- Implantation of the embryos into the wall of the uterus may not occur, even with the use of selective assisted hatching and/or genetic screening.

Laboratory. An event may occur in the laboratory resulting in loss or damage to some or all of the eggs or embryos. The Strong Fertility Center will take reasonable measures to maintain and monitor this equipment. However, despite their best efforts, equipment failure may result in the damage or loss of one or more of our (my) sperm, eggs or embryos. We (I) understand and agree that Strong Fertility Center shall be responsible only for acts of negligence on its part and the part of its employees, contractors, and consultants. The program will account honestly for all gametes and embryos.

Pregnancy Loss. Although pregnancy may be successfully established, there is still the possibility of miscarriage, ectopic pregnancy, stillbirth and/or congenital abnormalities (birth defects). Conceptions resulting from IVF/ET) have been associated with a slightly higher risk of pregnancy loss than pregnancies resulting from a natural conception. However, it is still unclear whether the risk is related to patients, medications, or laboratory procedures. It is possible that infertile couples differ from the general population, and it is not the technology that leads to the higher risk.

Ethical and religious considerations in infertility treatment

Infertility treatment can raise concerns and questions of an ethical or religious nature for some patients. The technique of in vitro fertilization (IVF) involves the creation of human embryos outside the body, and can involve the production of excess embryos and/or "high-order" multiple pregnancy

(triplets or more). We encourage patients and their spouses or partners who so desire to consult with trusted members of their religious or ethics community for guidance on their infertility treatment.

Psychosocial effects of infertility treatment

For those seeking treatment because of their own infertility, there can be psychological issues. A diagnosis of infertility can be a devastating and life-altering event that impacts many aspects of a patient's life. Infertility and its treatment can affect a patient and her spouse or partner medically, financially, socially, emotionally and psychologically. Feelings of anxiousness, depression, isolation, and helplessness are not uncommon among patients undergoing infertility treatment. Strained and stressful relations with spouses, partners, and other loved ones are not uncommon as treatment gets underway and progresses.

Our health care team is available to address the emotional, as well as physical symptoms that can accompany IVF treatment. In addition to working with our health care team to minimize the emotional impacts of this treatment, patients may also consider working with mental health professionals who are specially trained in the area of assisted reproductive technology.

While it is normal to experience emotional ups and downs when pursuing assisted reproductive technology, it is important to recognize when these feelings are of a severe nature. If you experience any of the following symptoms over a prolonged period of time, you may benefit from working with a mental health professional:

- Loss of interest in usual activities
- Depression that doesn't lift
- Strained interpersonal relationships
- Difficulty thinking of anything other than your infertility
- High levels of anxiety
- Diminished ability to accomplish tasks
- Difficulty with concentration
- Change in your sleep patterns
- Change in your appetite or weight
- Increased use of drugs or alcohol
- Thoughts about death or suicide
- Social isolation
- Persistent feelings of pessimism, guilt, or worthlessness
- Persistent feelings of bitterness or anger

Our health care team can assist you in locating a qualified mental health professional who is familiar with the emotional experience of infertility, or you can contact a national support group such as RESOLVE, (www.resolve.org, or Path2Parenthood ((www.path2parenthood.org.org).

Insurance coverage for any or all of the above procedures may not be available and we (I) will be personally responsible for all expenses of this treatment that are not covered by insurance.

Special Issues with the Use of Donor Eggs

Donor Identity.

The identity of the donor can be known or non-identity release donor. This is a joint decision of the donor and recipient.

If our donor is a non-identity release donor, we agree that we will never seek her identity, except as allowed for below or if a court orders otherwise. We (I) also understand that Strong Fertility Center will not reveal our identities to the donor except as allowed below, as required by statute, or if a final non-appealable court order orders otherwise. However, we (I) understand that if a child born from this donation has a medical or psychological need that might be met by the donor, then we may contact Strong Fertility Center and ask that our request be relayed to the donor. Such requests may be for a medical need such as a bone marrow transplant, or, once any child or children born from this donation are legal adults, a request may be made by the child or children for the identity of the donor to be revealed. The donor is under no obligation to consent to any request. We also understand Strong Fertility Center may be unable to reach the donor at any future date.

We understand that the offspring of any donation may request to learn of the identity of the donor when they reach adulthood. The donor is under no obligation to agree to this request, but is also not prohibited from agreeing. Furthermore, it is possible that a court could compel disclosure of the donor's identity at any time.

Strong Fertility Center will continue to honor its commitment to keep the anonymity of donors or recipients. Recent advances in technology can independently reveal the identity of a donor or recipient. Personalized genetic test kits (e.g. Ancestry.com) can discover genetic links among individuals that were previously not known. I acknowledge that true anonymity is no longer possible in the current climate and the donor may be contacted by the offspring in the future by means outside of the control of Strong Fertility Center.

Information on all cycles of Assisted Reproductive Technology treatment, along with data identifying recipients and women who undergo ART with their own eggs, is currently collected into a national database under the 1992 Fertility Clinic Success Rate and Certification Act. As part of this process, the Society for Assisted Reproductive Technology plans to begin to collect identifying information on all egg donors. As with recipient cycles and cycles for women using their own eggs, this information may be used to track outcomes. For this purpose, certain donor identifying information such as name, date of birth, and social security number may be reported to a Registry by SART member clinics for data aggregation purposes. ASRM guidelines currently require permanent records be kept for all egg donation cycles. Efforts to collect this information are intended to respect donation confidentiality and not to disclose confidential identifying information to recipients, donors, or offspring. Control of such information in the future may, however, depend on applicable law.

Parental Rights and Responsibilities.

We (I) understand and accept our (my) responsibilities for the care of any child resulting from the egg donation process, and it is our (my) intent to be the legal parent(s) of any child that results from the egg donation process, with all the rights and responsibilities that come with parenting. Under no circumstance will we (I) seek financial assistance from the donor or Strong Fertility Center. We (I) understand that neither the Strong Fertility Center nor the donor will assume any financial responsibility for the upbringing of any child resulting from the egg donation process under any circumstances. We (I) also assume responsibility for all costs associated with the use of donor eggs.

We (I) understand that that laws governing legal parentage of any child born through egg/embryo/sperm donation vary from state to state. Furthermore, such laws may apply to: children born in a given state; parents who reside in a given state; or the state where Strong Fertility Center is located. In some states, parents may obtain a pre-birth Court order establishing parental rights, in others, they may need to formally adopt the child (or children), and in others, there may be no option and/or requirement to establish legal parentage. The Strong Fertility Center does not offer legal advice on these matters and we (I) acknowledge and agree that we (I) must consult an attorney with expertise in family law related to assisted reproductive technologies in the relevant/applicable state(s).

Confidentiality.

We (I) understand and agree that, if we have an identified donor, aspects of our (my) medical care and conditions and that of the donor may be revealed and/or discerned as part of the treatment process.

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.

Additional Information

General IVF overviews available on the internet

www.reproductivefacts.org

www.sart.org/

www.cdc.gov/art/

www.resolve.org/site/PageServer

Effect of Woman's Age

Female age-related fertility decline. Committee Opinion No. 589. Fertility and Sterility 2014; 101:633-4.

Effect of Number of Oocytes Retrieved

Baker VL, Brown MB, Luke B, Conrad KP. Association of number of retrieved oocytes with live birth rate and birth weight: An analysis of 231,815 cycles of in vitro fertilization. Fertility and Sterility 2015; 103:931-8.

Effect of Infertility Diagnoses

Stern JE, Luke B, Tobias M, Gopal D, Hornstein MD, Diop H. Adverse pregnancy and birth outcomes by infertility diagnoses with and without ART treatment. Fertility and Sterility 2015; 103:1438-45.

Luke B, Stern JE, Kotelchuck M, Declercq E, Cohen B, Diop H. Birth outcomes by infertility diagnosis: Analyses of the Massachusetts Outcomes Study of Assisted Reproductive Technologies (MOSART). Journal of Reproductive Medicine 2015; 60:480-490.

Effect of Maternal Obesity

Luke B, Brown MB, Stern JE, Missmer SA, Fujimoto VY, Leach R. Female obesity adversely affects assisted reproductive technology (ART) pregnancy and live birth rates. Human Reproduction 2011; 26:245-252.

Obesity and reproduction: A committee opinion. Practice Committee of the American Society for Reproductive Medicine. Fertility and Sterility 2015; 104:1116-26.

Number of Embryos to Transfer

Elective single-embryo transfer. Practice Committee of the American Society for Reproductive Medicine and the Practice Committee of the Society for Assisted Reproductive Technology. Fertility and Sterility 2012; 97:835-42.

Criteria for number of embryos to transfer: a committee opinion. The Practice Committee of the American Society for Reproductive Medicine and the Practice Committee of the Society for Assisted Reproductive Technology. Fertil Steril 2013; 99(1):44-6.

Culturing Embryos to the Blastocyst Stage

Blastocyst culture and transfer in clinical assisted reproduction: A committee opinion. The Practice Committee of the American Society for Reproductive Medicine and the Practice Committee of the Society for Assisted Reproductive Technology. Fertil Steril 2013; 99:667-72.

Practice Committee of the American Society for Reproductive Medicine, and the Practice Committee of the Society for Assisted Reproductive Technology. Guidance on the limits to the number of embryos to transfer: A committee opinion. Fertility and Sterility 2017; 107:901-3.

Intracytoplasmic sperm injection

Genetic considerations related to intracytoplasmic sperm injection (ICSI). The Practice Committee of the American Society for Reproductive Medicine and the Practice Committee of the Society for Assisted Reproductive Technology. Fertil Steril 2006; 86 (suppl 4): S103-S105.

Intracytoplasmic sperm injection (ICSI) for non-male factor infertility: a committee opinion. Practice Committees of the American Society for Reproductive Medicine and Society for Assisted Reproductive Technology. Fertility and Sterility 2012; 98:1395-9.

Wen J, Jiang J, Ding C, Dai J, Liu Y, Xia Y, Liu J, Hu Z. Birth defects in children conceived by in vitro fertilization and intracytoplasmic sperm injection: a meta-analysis. Fertility and Sterility 2012; 97(6): 1331-1337 e4.

Embryo hatching

The role of assisted hatching in in vitro fertilization: a guideline. A Committee opinion. The Practice Committee of the American Society for Reproductive Medicine and the Practice Committee of the Society for Assisted Reproductive Technology. Fertil Steril 2014; 102:348-51.

Luke B, Brown MB, Wantman E, Stern JE. Factors associated with monozygosity in assisted reproductive technology (ART) pregnancies and the risk of recurrence using linked cycles Fertility and Sterility, 2014; 101:683-9.

Ovarian Hyperstimulation

Prevention and treatment of moderate and severe ovarian hyperstimulation syndrome: a guideline. The Practice Committees of the American Society for Reproductive Medicine. Fertil Steril 2016; 106:1634-47.

Luke B, Brown MB, Morbeck DE, Hudson SB, Coddington CC, Stern JE. Factors associated with ovarian hyperstimulation syndrome (OHSS) and its effect on Assisted Reproductive Technology (ART) treatment and outcome. Fertility and Sterility 2010; 94:1399-404.

Risks of pregnancy

Declercq E, Luke B, Belanoff C, Cabral H, Diop H, Gopal D, Hoang L, Kotelchuck M, Stern JE, Hornstein MD. Perinatal Outcomes Associated with Assisted Reproductive Technology: the Massachusetts Outcomes Study of Assisted Reproductive Technologies (MOSART). Fertility and Sterility 2015; 103:888-895.

Risk of borderline and invasive tumours after ovarian stimulation for *in vitro fertilization* in a large Dutch cohort. FE van Leeuwen, H Klip, et al. Human Reproduction, 2011;26(12):3456-65.

Luke B, Brown MB, Spector LG, Missmer SA, Leach RE, Williams M, Koch L, Smith Y, Stern JE, Ball GD, Schymura MJ. Cancer in women after assisted reproductive technology. Fertility and Sterility 2015; 104:1218-26.

Risks to offspring

Fauser BCJM, Devroey P, Diedrich K, Balaban B, Bonduelle M, Delemarre-van de Waal HA, Estella C, Ezcurra D, Geraedts JPM, Howles CM, Lerner-Geva L, Serna J, Wells D, Evian Annual Reproduction Workshop Group 2011. Health outcomes of children born after IVF/ICSI: A review of current expert opinion and literature. Reproductive BioMedicine Online 2014; 28:162-182.

Multiple pregnancy associated with infertility therapy: an American Society for Reproductive Medicine Practice Committee opinion. Practice Committees of the American Society for Reproductive Medicine Fertil Steril 2012; 97:825-34.

Imprinting diseases and IVF: A Danish National IVF cohort study. Lidegaard O, Pinborg A and Anderson AN. Human Reproduction 2005; 20(4):950-954.

Amor DJ and Halliday J. A review of known imprinting syndromes and their association with assisted reproduction technologies. Human Reproduction 2008; 23:2826-34.

Bergh C, Wennerholm U-B. Obstetric outcome and long-term follow up of children conceived through assisted reproduction. Best Practice & Research Clinical Obstetrics and Gynaecology (2012), doi:10.1016/j.bpobgyn.2012.05.001.

Wennerholm U-B, Söderström-Anttila V, Bergh C, Aittomäki K, Hazekamp J, Nygren K-G, Selbing A, Loft A. Children born after cryopreservation of embryos or oocytes: A systematic review of outcome data. Human Reproduction 2009; 24:2158-72.

Kopeika J, Thornhill A, Khalaf Y. The effect of cryopreservation on the genome of gametes and embryos: principles of cryobiology and critical appraisal of the evidence. Human Reproduction Update 2015; 21:209-227.

Birth Defects

Källén B, Finnström O, Lindam A, Nilsson E, Nygren K-G, Otterblad PO. Congenital malformations in infants born after in vitro fertilization in Sweden. Birth Defects Research (Part A) 2010; 88:137-43.

Davies MJ, Moore VM, Willson KJ, Van Essen P, Priest K, Scott H, Haan EA, Chan A. Reproductive Technologies and the risk of birth defects. N Engl J Med 2012;366:1803-13.

Boulet SL, Kirby RS, Reefhuis J, Zhang Y, Sunderam S, Cohen B, Bernson D, Copeland G, Bailey MA, Jamieson DJ, Kissin DM. Assisted reproductive technology and birth defects among liveborn infants in Florida, Massachusetts, and Michigan, 2000-2010. JAMA Pediatrics 2016; Published online April 04, 2016. doi:10.1001/jamapediatrics.2015.4934

We (I), expect this procedure to be performed with not less than the customary standard of care. We (I) understand the risks and benefits as outlined above. We (I) have had the opportunity to review this treatment and ask questions of our (my) physician concerning the alternative options to utilization of donated eggs, including adoption and no treatment. The full egg donation process has been explained to us (me), together with the known risks. We (I) understand the explanation that has been given to us. We (I) have had the opportunity to ask any questions we (I) might have and those questions have been answered to our (my) satisfaction. Any further questions may be addressed to the Strong Fertility Clinic staff. We (I) acknowledge that utilization of donated eggs is being performed at our (my) request and with our (my) consent.

We (I), the undersigned, request, authorize and consent to the **utilization of donated eggs** by the Strong Fertility Center, and as appropriate, its employees, contractors, and consultants and authorized agents for the purpose of achieving a pregnancy.

If signed out of the office:

X _____ _____
Patient Signature Date

_____ _____
Patient Name Date of Birth

Notary Public
Sworn and subscribed before me on this _____ day of _____, _____.

_____ _____
Notary Signature Date

X _____ _____
Spouse / Partner Signature Date

_____ _____
Spouse / Partner Name Date of Birth

Notary Public
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 who signed this document is personally known to me and appears to be of sound mind and acting of his or her own free will. He or she signed (or asked another to sign for him or her) this document in my presence.

Witness Name: _____

Witness Signature: _____

Date: _____