Recipients of Donor Eggs Info & Consent

**These template documents were revised before the US Supreme Court decision in *Dobbs v. Jackson* (which repealed Roe v. Wade), and therefore, SART has not reviewed the template documents and did not make any changes based on the *Dobbs* decision. SART strongly recommends that before any SART template document is put into use in a Member's practice, the document should be reviewed by the Member's local legal counsel to ensure that the language conforms to current federal, state and local laws as these may have recently changed or are in the process of being changed.**

DESCRIPTION

This document informs Recipients about Donor Egg therapy in detail, including the risks to the donor, recipient, and offspring. It then asks the Recipient to consent to this therapy with its risks.

TARGET

* All Recipients using Donor Eggs

RELEASE NOTES

* This is the 2nd revision of this document
* Risks to intended parent(s) and offspring updated based on current literature
* PGT language included
* Page 1 allows identification of the intended parent(s) and their planned treatment options (i.e., non-identified vs directed donor, fresh vs frozen eggs, identity disclosure choice).
* Revised guidelines (2017) for maximum number of embryos to transfer included
* Wording shortened and simplified where possible
* Signature page allows for Witness as well as Notary verification.

TO DO

* Modify this document according to local needs and preferences.
* Replace “CLINIC” with your program’s name throughout
* Get egal review to assure conformance with State and local laws and regulations

***DISCLAIMER.***

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Recipients of Donor Eggs

Process, Risks, Consent

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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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 (“directed”) or unknown (“non-identified”), and the eggs can be fresh or previously frozen.

Treatment Type: o Non-identified o Directed (ID: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)

 o Fresh eggs o Frozen eggs (Egg Bank)

Identity Disclosure: o None o Open now o Known when an adult

Steps in the Process

First an egg donor needs to be identified, screened, and her eggs retrieved. This involves a screening process that is regulated by the FDA and follows ASRM recommendations. The FDA portion of donor screening, called “donor eligibility determination,” focuses on minimizing risk of infectious disease transmission. The ASRM portion of FDA screening focuses on donor physical and psychological health.

Screening of Egg Donor

The medical, psychological, genetic, and family history of possible egg donors are evaluated to make sure they do not have any conditions that would disqualify them from donation or increase the risk of an adverse health outcome for the child. No screening or testing regimen is perfect, one’s health can evolve over time, and many diseases are not inherited from a single gene mutation, so it remains possible for children from donor eggs to have medical problems or birth defects just as would be the case in non-donor egg pregnancies. In addition to the ASRM recommended testing, the FDA requires that all donors are also tested for infectious diseases. This involves an extensive questionnaire, a physical exam, and blood tests. To be eligible to be a non-identified donor, all the FDA required testing must be normal.

Ovarian Stimulation of the Donor

To donate eggs, a donor undergoes the first part of a standard IVF cycle. Hormone medications are used to stimulate the ovary to help multiple follicles mature; progress is monitored with vaginal ultrasounds and blood tests. The donor then has an egg retrieval during which a transvaginal ultrasound probe is used to see the ovaries and the egg-containing follicles within the ovaries and a long needle is guided into each follicle to drain the fluid that contains the egg.

In Vitro Fertilization

The eggs, whether fresh or thawed, are kept in conditions that support their needs and growth.  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 (or an intravaginal culture device), where they remain to develop.

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, and are called cleavage stage embryos.
* 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.
* Day 5 or 6: Normal embryos now have 100 -200 cells, and are called blastocysts. They have a fluid-filled cavity and a small cluster of cells on the inside called the inner cell mass, which forms the fetus.

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 into Recipient or Carrier

* After a few days of development, the best embryo is 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 catheter.
* 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 embryo is 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 your donor is under age 35, and the best embryo looks normal, then in most cases only one embryo should be transferred. 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.

Hormonal Support of Uterus

* For a pregnancy to occur, the embryo(s) must attach to the lining of the uterus (endometrium). 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 appropriate in some cases:

 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

* *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.
* *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.
* *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.
* *Misdiagnosis.* The test may give the wrong result, and say that a normal embryo is abnormal, or that an abnormal embryo is 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.

   Freezing

* Freezing of eggs or embryos provides an additional chance for pregnancy in the future.
* Freezing eggs and embryos do not always survive the process of freezing and thawing.
* 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 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 2018, 8% 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.

Other Potential Infant Risks

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 often born with below average 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.

Limits to the Success of the Process

There are several 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.
* A non-identified 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 later.
* A non-identified 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 the eggs or embryos. The CLINIC 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 The CLINIC 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.

Special Issues with the Use of Donor Eggs

Donor Identity.

The identity of the donor can be known (“directed”) or unknown (“non-identified”). This is a joint decision of the donor and recipient.

If our donor is non-identified, 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 the CLINIC 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 the CLINIC 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 the CLINIC 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.

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 CLINIC. We (I) understand that neither the CLINIC 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 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 each state; parents who reside in a given state; or the state where a CLINIC 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 CLINIC 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.

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 CLINIC staff or Dr. John Smith at (123) 456-7890. 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 CLINIC, and as appropriate, its employees, contractors, and consultants and authorized agents for the purpose of achieving a pregnancy.

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

===================================================================

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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_