Consent to Thaw Embryo(s) for the purpose of Frozen Embryo Transfer

Process, Risk, and Consent

In Vitro Fertilization (IVF) has become an established treatment for many forms of infertility or for the purposes of fertility preservation. The main goal of IVF is to allow a patient or couple the opportunity to start or add to a family. This is an elective procedure designed to result in the patient’s pregnancy when other treatments have failed or are not appropriate. IVF may and often results in the availability embryos for cryopreservation allowing for future use.

Once biological specimens such as embryos are cryopreserved using the In Vitro Fertilization (IVF) process, additional processes and procedures must be undertaken both in the laboratory as well as in the recipient in order to prepare these specimens for successful transfer into the uterus of a woman. The processes for each are outlined below.

This consent reviews the process necessary for preparation of cryopreserved embryos for transfer into a uterus, including potential risks that this treatment might pose to you and your offspring. While best efforts have been made to disclose all known risks, there may be risks encountered during the thawing, laboratory manipulation, and transfer process that are not yet clarified or even suspected at the time of this writing.

I/We understand the following are basic steps and events to be taken for the thaw and transfer process:

- Completion of preliminary screening as deemed appropriate by your physician (may include testing for infectious diseases, autoimmune tests when indicated, endocrine evaluation, semen testing, assessment of uterine cavity with sonohysterogram and/or hysteroscopy as well as mock uterine stimulation, Pap’s smear, mammogram, cervical cultures, and possible genetic testing and/or psychological consultation).

- IVF Education and Consent Consultation with the clinical staff, and an injection training session. All injectable prescriptions need to be filled prior to this training session and brought to the session. Any one administering injections also need to attend this session, unless previously attended. Additional medications not initially prescribed may be ordered later in the cycle.

- Treatment with transdermal, oral, vaginal, and/or injectable fertility drugs, hormonal agents, and other medications (including but not limited to: oral contraceptives, antibiotics, valium, Lupron, estrogen in various forms, progesterone, and methylprednisone,) to suppress ovarian stimulation, promote development and growth of the uterine endometrium, and facilitate the best overall environment for embryo transfer.

- Serial evaluation of hormonal blood levels (estradiol, progesterone) and transvaginal ultrasounds to assess the efficacy of the uterine stimulation medications. *(Appointment visits will be scheduled before 10 AM)*

- Ultrasound guided embryo transfer will be performed by one of the AFC physicians.

- Embryo transfer will occur on the same day as blastocyst thaw. You will walk to and from the procedure room, and unless you are undergoing acupuncture, discharge from AFC will occur shortly after the transfer is completed. Home rest for the remainder of that day is optional at your own discretion.

- Progesterone and Estradiol blood tests approximately three days after day of embryo transfer and serial blood pregnancy tests ~ 8 days to 3 weeks following embryo transfer.

- Two to three OB ultrasounds will be performed assuming successful pregnancy.
Frozen Embryo Transfer Procedures

Medications for Frozen Embryo Transfer and Hormonal support of the uterine lining

- Successful attachment of embryo(s) to the uterine lining depends on adequate hormonal support.
- Progesterone, given by the intramuscular, oral, and/or vaginal route, is routinely given for this purpose.

Successful attachment of embryos to the uterine lining (endometrium) depends on adequate hormonal support of the lining. The critical hormones in this support are progesterone and estradiol. Normally, the ovary makes sufficient amounts of both hormones. However, in IVF cycles, this support is not always adequate. Therefore, progesterone is routinely given, and in some cases, estradiol is also prescribed. Progesterone is given by the intramuscular or vaginal route. Estradiol is given by the oral, vaginal, trans-dermal or intramuscular route. The duration of this support is from 2 to 10 weeks.

Medications may include the following (not a complete list):

- **GnRH-agonists (leuprolide acetate) (Lupron®):** This medication is taken by injection. There are two forms of the medication: A short acting medication requiring daily injections and a long-acting preparation lasting for 1-3 months. The primary role of this medication is to prevent a premature LH surge, which could result in the release of eggs before they are ready to be retrieved. Since GnRH-agonists initially cause a release of FSH and LH from the pituitary, they can also be used to start the growth of the follicles or initiate the final stages of egg maturation. Though leuprolide acetate is an FDA (U.S. Food and Drug Administration) approved medication, it has not been approved for use in IVF, although it has routinely been used in this way for more than 20 years. Potential side effects usually experienced with long-term use include, but are not limited to: hot flashes, vaginal dryness, bone loss, nausea, vomiting, skin reactions at the injection site, fluid retention, muscle aches, headaches, and depression. No long term or serious side effects are known. Since GnRH-a are oftentimes administered after ovulation, it is possible that they will be taken early in pregnancy. The safest course of action is to use a barrier method of contraception (condoms) the month you will be starting the GnRH-a. GnRH-a has not been associated with any fetal malformations, however you should discontinue use of the GnRH-a immediately if pregnancy is confirmed.

- **Progesterone and Estradiol:** Progesterone and estradiol are hormones normally produced by the ovaries after ovulation and required to develop and maintain the uterine endometrium for implantation of embryos. For the purposes of an embryo transfer from embryos derived from either frozen eggs or embryos, supplemental progesterone and estradiol are given to ensure adequate hormonal development and support of the uterine lining. Progesterone is usually given by injection or by the vaginal route (Endometrin®, Crinone®, Prochieve®, Prometrium®, or pharmacist-compounded oil based injections or suppositories). Progesterone is often continued for some weeks after a pregnancy has been confirmed. Progesterone has not been associated with an increase in fetal abnormalities. Side effects of progesterone include depression, sleepiness, allergic reaction, and if given by intra-muscular injection, includes the additional risk of infection or pain at the injection site. Estradiol, if given, can be by oral, trans-dermal, intramuscular, or vaginal administration. Side effects of estradiol include nausea, irritation at the application site if given by the trans-dermal route and the risk of blood clots or stroke.
- **Oral contraceptive pills**: Some treatment protocols include oral contraceptive pills to be taken for 2 to 4 weeks before gonadotropin injections are started in order to suppress hormone production or to schedule a cycle. Side effects include unscheduled bleeding, headache, breast tenderness, nausea, swelling and the risk of blood clots or, very rarely, stroke.

- **Other medications**: Antibiotics may be given for a short time during the treatment cycle to reduce the risk of infection associated with egg retrieval or embryo transfer. Antibiotic use may be associated with vaginal yeast infection, nausea, vomiting, diarrhea, rashes, sensitivity to the sun, and allergic reactions. Anti-anxiety medications or muscle relaxants may be recommended prior to the embryo transfer. The most common side effect is drowsiness. Other medications such as steroids, heparin, low molecular weight heparin or aspirin may also be included in the treatment protocol.

### In Vitro Fertilization using Cryopreserved Eggs and Embryo Culture

#### Starting with Cryopreserved Embryos

In most cases, embryos will have been frozen at the blastocyst stage of development (5-6 days after fertilization or approximately 80-100 cells). In more rare circumstances, embryos may have been frozen after initial fertilization of the egg “2PN stage” or after 3 days after fertilization (6-10 cells).

In cases where freezing occurred earlier than at the blastocyst stage of development, the embryos must be thawed in the laboratory and cultured in special media for 2-5 days to ensure adequate survival and cell growth and division.

Published reports indicate approximately 95-98% of all cryopreserved blastocysts survive the thawing process if they were initially frozen using the most current flash freezing techniques known as “vitrification”. However, it is difficult or impossible to predict how many of the thawed embryos will survive and/or continue to develop and be suitable for transfer.

Embryo transfer will ONLY occur if the thawed embryo(s) are determined to be medically suitable for transfer to the uterus. Embryo(s) will NOT be transferred into the patient’s uterus if the embryo(s) do not survive the thawing process and/or do not develop. **Embryos that do not divide and/or survive the freeze/thaw process will be discarded.**

#### Embryo transfer

- When starting with cryopreserved embryos, embryos are considered to be viable and suitable for transfer if at least 50% of the cells survive the thawing process.
- The number chosen for transfer influences the pregnancy rate and the multiple pregnancy rate.
- The age of the egg used to create the embryo, the visual appearance of the developing embryo, and the internal genetic composition of the embryo have the greatest influences on pregnancy outcome.
- Using ultrasound guidance, embryos are placed in the uterine cavity with a thin tube.
One or more embryos are selected for transfer to the uterine cavity. In the case of embryo thaw, the number of embryos thawed and intended for transfer will be predetermined by the recipient(s) in consultation with the physician and as noted on this consent form. Embryos are placed in the uterine cavity with a thin tube (catheter). Ultrasound guidance may be used to help guide the catheter or confirm placement through the cervix and into the uterine cavity. Although the possibility of a complication from the embryo transfer is very rare, risks include infection and loss of, or damage to, the embryos.

The number of embryos transferred influences the pregnancy rate and the multiple pregnancy rate. The age of the woman and the appearance of the developing embryo have the greatest influence on pregnancy outcome and the chance for multiple pregnancy. While it is possible, it is unusual to develop more fetuses than the number of embryos transferred. It is critical to discuss with your doctor the number to be transferred before the transfer is done.

In an effort to help curtail the problem of multiple pregnancies (see multiple pregnancies), national guidelines published in 2017 recommend limits on the number of embryos to transfer (see Tables below). These limits should not necessarily be viewed as a recommendation on the number of embryos to transfer. These limits differ depending on the developmental stage of the embryos and the quality of the embryos and take into account the patient’s personal history.

At AFC, in women under age 35 who have at least 3 blastocysts of good quality that develop and are available for transfer on day 5, elective SINGLE BLASTOCYST is strongly encouraged; AFC and AARL internal data support minimal if any compromise in subsequent pregnancy rate when compared to transfer of two or more embryos in the same population, however, with drastically reduced rates of multiple pregnancies.

**Recommended MAXIMUM LIMITS on the number of embryos to transfer (ASRM 4/2017)**

<table>
<thead>
<tr>
<th></th>
<th>Age &lt; 35</th>
<th>Age 35-37</th>
<th>Age 38-40</th>
<th>Age &gt;40</th>
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</thead>
<tbody>
<tr>
<td><strong>Embryos (Day 3)</strong></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>--Euploid</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>--Other favorable</td>
<td>1</td>
<td>1</td>
<td>≤3</td>
<td>≤4</td>
</tr>
<tr>
<td>--All Others</td>
<td>≤2</td>
<td>≤3</td>
<td>≤4</td>
<td>≤5</td>
</tr>
<tr>
<td><strong>Blastocysts (Day 5)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>--Euploid</td>
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<td>1</td>
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<td>--All others</td>
<td>≤2</td>
<td>≤2</td>
<td>≤3</td>
<td>≤3</td>
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</tbody>
</table>

**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 from the shell that surrounds them.

The cells that make up the early embryo are enclosed within a flexible membrane (shell) called the zona pellucida. During normal development, a portion of this membrane dissolves, allowing the embryonic cells to escape or “hatch” out of the shell. Only upon hatching can the embryonic cells implant within the wall of the uterus to form a pregnancy. Assisted hatching is the laboratory technique in which an embryologist makes an artificial opening in the shell of the embryo. The hatching is usually performed on the day of transfer, prior to loading the embryo into the transfer catheter. The opening can be made by mechanical means (slicing with a needle or burning the shell with a laser) or chemical means by dissolving a small hole in the shell with a dilute acid solution.
In the case of frozen embryos, assisted hatching is routinely performed due to the hardening of the embryo membrane associated with the freezing process; this technique has been shown to improve implantation rates, and ultimately, live birth rates. In the case of fresh embryo transfers, some programs have also incorporated artificial or "assisted hatching" into their treatment protocols in certain situations because they believe it improves implantation rates, and ultimately, live birth rates although definitive evidence of this is lacking.

Risks that may be associated with assisted hatching include damage to the embryo resulting in loss of embryonic cells, or destruction or death of the embryo. Artificial manipulation of the zygote may increase the rates of monozygotic (identical) twinning which are significantly more complicated pregnancies. There may be other risks not yet known.

**Risks to the Woman**

**Risks of Pregnancy**

Pregnancies that occur with IVF are associated with increased risks of certain conditions (see Table below from the Executive Summary of a National Institute of Child Health and Human Development Workshop held in September 2005, as reported in the journal *Obstetrics & Gynecology*, vol. 109, no. 4, pages 967-77, 2007). Some of these risks stem from the higher average age of women pregnant by IVF and the fact that the underlying cause of infertility may be the cause of the increased risk of pregnancy complications. This was demonstrated in an Australian study that reviewed adverse obstetric and perinatal outcomes in sub-fertile women conceiving without ART (see Table below). There may be additional risks related to the IVF procedure per se, but it is difficult to assign the relative contributions.

### Potential Risks in Singleton IVF-conceived Pregnancies

<table>
<thead>
<tr>
<th></th>
<th>Absolute Risk (%) in IVF-conceived Pregnancies</th>
<th>Relative Risk (vs. non IVF-conceived Pregnancies in a control population)</th>
<th>Relative Risk of Non-IVF Infertile Patients (vs. control population)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-eclampsia</td>
<td>10.3%</td>
<td>1.6 (1.2–2.0)</td>
<td>1.29 (1.02-1.61)</td>
</tr>
<tr>
<td>Placenta previa</td>
<td>2.4%</td>
<td>2.6 (1.5–5.4)</td>
<td>2.66 (2.22-3.01)</td>
</tr>
<tr>
<td>Placental abruption</td>
<td>2.2%</td>
<td>2.4 (1.1–5.2)</td>
<td>2.44 (2.01-2.88)</td>
</tr>
<tr>
<td>Gestational diabetes</td>
<td>6.8%</td>
<td>2.0 (1.4–3.0)</td>
<td>2.0 (1.25-2.75)</td>
</tr>
<tr>
<td>Cesarean delivery *</td>
<td>26.7%</td>
<td>2.1 (1.7–2.6)</td>
<td>2.14 (1.37-2.77)</td>
</tr>
</tbody>
</table>

In this table, the Absolute risk is the percent of IVF Pregnancies in which the risk occurred. The Relative Risk is the risk in IVF versus the risk in non-IVF, non-infertile pregnancies; for example, a relative risk of 2.0 indicates that twice as many IVF pregnancies experience this risk as compared to non-IVF pregnancies. However, the third column indicates the increased risk of adverse outcome in infertile women conceiving without ART suggesting that being infertile increases the risk of adverse outcomes unrelated to ART/IVF. The numbers in parentheses (called the "Confidence Interval") indicate the range in which the actual Relative Risk lies. * Please note that most experts believe the rate of Cesarean delivery to be well above the 26.7% rate quoted here.

Multiple gestations, which account for 30% of IVF pregnancies, increase the risk of pregnancy complications. The most important maternal complications associated with multiple gestations are preterm labor and delivery, pre-eclampsia, and gestational diabetes. Placenta previa (placenta extends over the cervical opening), vasa previa (one or more of the blood vessels extends over the cervical opening), and placental abruption (premature separation of the placenta) are also more common in multiple gestations. Postpartum hemorrhage may complicate 12% of multifetal deliveries. Having triplets or more increases the risk of more significant complications including post-partum hemorrhage and transfusion. Other complications of multiple gestations include gall bladder problems, skin problems, excess weight gain, anemia, excessive nausea and vomiting, and exacerbation of pregnancy-associated gastrointestinal symptoms.

Although embryos are transferred directly into the uterus with IVF, ectopic (tubal, cervical and abdominal) pregnancies have occurred either alone or concurrently with a normal intra-uterine pregnancy. These abnormal pregnancies oftentimes require medical treatments with methotrexate (a weak chemotherapy drug) or surgery to treat the abnormal pregnancy.
Risks to Offspring

- IVF babies seem to be at a slight increased risk for birth defects.
- The risk for a multiple pregnancy is significantly higher for patients undergoing IVF, even when only one embryo is transferred.
- Multiple pregnancies are the greatest risk for babies following IVF.
- Some risk may also stem from the underlying infertile state, or from the IVF techniques, or both.

Overall Risks: Since the first birth of an IVF baby in 1978, more than 5 million children have been born worldwide following IVF treatments. Numerous studies have been conducted to assess the overall health of IVF children and the majority of studies on the safety of IVF have been reassuring. A major problem in interpreting the data arises from the fact that comparing a group of infertile couples to a group of normally fertile couples is not the proper comparison to make if one wants to assess the risk that IVF technology engenders. Infertile couples, by definition, do not have normal reproductive function and might be expected to have babies with more abnormalities than a group of normally fertile couples. This said, even if the studies suggesting an increased risk to babies born after IVF prove to be true, the absolute risk of any abnormal outcome appears to be small. In addition, singletons conceived with IVF tend to be born slightly earlier than naturally conceived babies (39.1 weeks as compared to 39.5 weeks). IVF twins are not born earlier or later than naturally conceived twins. The risk of a singleton IVF conceived baby being born with a birth weight under 5 pounds nine ounces (2500 grams) is 12.5% vs. 7% in naturally conceived singletons.

Birth Defects: The risk of birth defects in the normal population is 2-3%, and is slightly higher among infertile patients. Most of this risk is due to delayed conception and the underlying infertility issues. In a recent large study performed in Australia (see reference), the risk of birth defects was not increased among women who had routine IVF treatment, but was higher among those who employed ICSI as part of the treatment. No higher risk was seen in frozen embryo transfer and donor egg cycles.

Imprinting Disorders. These are rare disorders having to do with whether a maternal or paternal gene is inappropriately expressed. In two studies of children with the imprinting disorder called Beckwith-Weidemann Syndrome, more were born after IVF than expected. A large Danish study, however, found no increased risk of imprinting disorders in children conceived with the assistance of IVF. Since the incidence of this syndrome in the general population is 1/15,000, even if there is a 2 to 5-fold increase to 2-5/15,000, this absolute risk is very low.

Childhood cancers. Most studies have not reported an increased risk with the exception of retinoblastoma: In one study in the Netherlands, five cases were reported after IVF treatment which is 5 to 7 times more than expected. Further studies have not supported this finding.

Infant development. In general, studies of long-term developmental outcomes have been reassuring so far; most children are doing well. However, these studies are difficult to do and suffer from limitations. A more recent study with better methodology reports an increased risk of cerebral palsy (3.7 fold) and developmental delay (4 fold), but most of this stemmed from the prematurity and low birth weight that was a consequence of multiple pregnancy.

Risks of a Multiple Pregnancy: Currently, more than 30% of IVF pregnancies are twins or higher-order multiple gestations (triplets or greater), and about half of all IVF babies are a result of multiple gestations. Identical twinning occurs in 1.5% to 4.5% of IVF pregnancies, and may occur more frequently after blastocyst transfer.

Prematurity accounts for most of the excess perinatal morbidity and mortality associated with multiple gestations. IVF twins deliver on average three weeks earlier and weigh 1,000 gm less than IVF singletons. Triplet (and greater) pregnancies deliver before 32 weeks (7 months) in almost half of cases. Fetal growth problems and discordant growth among the fetuses also result in perinatal morbidity and mortality. Multifetal pregnancy reduction (where one or more fetuses are terminated) reduces, but does not eliminate, the risk of these complications.

Fetal death rates for singleton, twin, and triplet pregnancies are 4.3 per 1,000, 15.5 per 1,000, and 21 per 1,000, respectively. The death of one or more fetuses in a multiple gestation (vanishing twin) is more common in the first trimester and may be observed in up to 25% of pregnancies after IVF. Loss of a fetus in the first trimester is unlikely to adversely affect the surviving fetus.
Multiple fetuses that share the same placenta, as in most identical twins, have additional risks. Twin-twin transfusion syndrome, in which excess or insufficient amniotic fluid results from an imbalance of circulation between the fetuses, may occur in up to 20% of twins sharing a placenta. Twins sharing the same placenta have a higher frequency of birth defects compared to twins with two placentas. After the first trimester, death of one fetus in a twin pregnancy is more common with a shared placenta and may cause harm to the remaining fetus.

Long-term consequences of multiple gestations include the major complications of prematurity (cerebral palsy, retinopathy of prematurity, and chronic lung disease), as well as those of fetal growth restriction (polycythemia, hypoglycemia, necrotizing enterocolitis). It is unclear to what extent multiple gestations themselves affect neuro-behavioral development in the absence of these complications. At mid-childhood, prematurely born offspring from multiple gestations have lower IQ scores, and multiple birth children have an increase in behavioral problems compared with singletons. It is not clear to what extent these risks are affected by IVF per se.

The Option of Multifetal Pregnancy Reduction: The greater the number of fetuses within the uterus, the greater is the risk for adverse perinatal and maternal outcomes. Patients with more than twins are faced with the options of continuing the pregnancy with all risks previously described, terminating the entire pregnancy, or undergoing a procedure called multifetal pregnancy reduction. By reducing the number of fetuses, multifetal pregnancy reduction (MFPR) decreases risks associated with preterm delivery, but often creates important ethical dilemmas. Pregnancy loss is the main risk of MFPR. However, current data suggest that such complications have decreased as experience with the procedure has grown. The risk of loss of the entire pregnancy after MFPR is approximately 1%, although this risk increases when the number of fetuses prior to the procedure is greater than three.

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). Patients and their spouses or partners who so desire are encouraged to consult with trusted members of their religious or ethics community for guidance on their infertility treatment.

Psychosocial Effects of Infertility Treatment

A diagnosis of infertility can be a devastating and life-altering event that impacts on 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 anxiety, 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.

Rearing of twins and high-order multiples may generate physical, emotional, and financial stresses; and the incidence of maternal depression and anxiety is increased in women raising multiples.

Patients may consider working with mental health professionals who are specially trained in the area of infertility care, as well as with their health care team, to minimize the emotional impact of infertility treatments. National support groups are also available, such as RESOLVE, (www.resolve.org, Tel. 1-888-623-0744) or The American Fertility Association (AFA), (www.theafa.org, Tel: 1-888-917-3777).

Reporting Outcomes

The 1992 Fertility Clinic Success Rate and Certification Act requires the Centers for Disease Control and Prevention (CDC) to collect cycle-specific data as well as pregnancy outcome on all assisted reproductive technology cycles performed in the United States each year and requires them to report success rates using these data. Consequently, data from my/our IVF procedure will be provided to the CDC, and to the Society of Assisted Reproductive Technologies (SART) of the American Society for Reproductive Medicine (ASRM) (if my/our clinic is a member of this organization). The CDC may request additional information from the treatment center or contact me/us directly for additional follow-up. Additionally, my/our information may be used and disclosed in accordance with HIPAA guidelines in order to perform research, data aggregation and/or quality control. All information used for research will be de-identified prior to publication. De-identification is a process intended to prevent the data associated with my/our treatment being used to identify me/us as individuals.
Summary – Thawing Embryos with Intent to Transfer

Success rates with frozen embryo transfer are dependent on individual factors and may range from less than 10% to more than 70%.

My/our initials and signatures on this document acknowledges that I/we have read and fully understand this document, accept all the responsibilities, conditions, and risks associated with the procedures, and confirm my/our voluntary participation in the procedures outlined and discussed in this document and as noted in the Embryo Thawing and Transfer Plan on page 9, as well as the following stipulations:

- I/We understand that the Advanced Fertility Care physician, and the IVF Laboratory (Arizona Advanced Reproductive Laboratory, LLC) cannot and do not guarantee the results of this procedure and we recognize the possibility of not becoming pregnant or not delivering a baby after transfer of the embryo(s). I/We understand that pregnancy may not occur for any of the following reasons: embryos may not survive the freezing/thawing process, the embryo(s) may not cleave and develop normally, an uncommon laboratory event may result in the loss of or damage to the embryo(s), implantation may not occur, equipment failure or staff error could occur, and any other unforeseen circumstances may affect the viability of the embryo(s).

- I/We have been assured that all information about us obtained during this procedure will be handled confidentially and that neither our identity nor our specific medical details will be revealed without our prior written consent. We acknowledge that specific anonymous medical details may be revealed in professional publications and to the SART licensing board as long as our identity is concealed. In addition, it is mandatory that data from our ART procedure be provided to the Centers for Disease Control and Prevention (CDC) as required by law and protected under the provisions of the Public Health Service Act, Section 308(d) excluding disclosure of identifying information without your consent.

- I/We agree to pay all fees associated with this procedure. Insurance may not cover any or part of the procedures. By our initials below and signatures on this consent, I/We agree that I/we will be responsible for all expenses resulting from this treatment. These expenses may consist of the surgery center charges, laboratory charges, anesthesia charges, and the physician's professional fees. Should I/we suffer any physical injury as the result of participation in the embryo transfer procedure, AFC and staff will make available any treatment and necessary facilities, emergency treatment, and professional services. However, these additional treatments will incur additional expenses not covered by our payment of fees for the thawing and embryo transfer procedures. I/We understand that in the event of injury resulting from this procedure, Advanced Fertility Care is not able to offer financial compensation or to absorb the costs of medical treatment.

- I/We hereby agree and acknowledge that any of our sperm, oocytes, or embryos, which the Advanced Fertility Care determines in reasonable medical judgment, is non-viable or not medically suitable for transfer may be disposed of in accordance with the Advanced Fertility Care IVF Program policies.

- I/We acknowledge parentage for any children resulting from this cycle and assume legal and moral responsibility for their well-being. Furthermore, I understand no guarantee has been made of the physical and/or mental condition of children resulting from this cycle.
Embryo Thawing and Transfer Plan

My/Our selections below, along with our initials and signatures on this document indicate our desired plan for treatment as previously discussed with my/our physician.

Desire and Consent to Embryo Thaw and Transfer

At Advanced Fertility Care/Arizona Advanced Reproductive Laboratory our policy is to always select the highest quality embryo(s) for transfer, unless you are eligible for and desire family balancing.

Choose only ONE option below:

- ☐ Standard Frozen Embryo Transfer
  - I/We authorize and consent to the thaw and transfer of: ☐ 1 (one) Embryo – usual recommended
  - ☐ 2 (two) Embryos*

- ☐ Desire Family Balancing:
  - ☐ ______________ *
  - * requires physician approval

You must meet ALL of these criteria to be eligible:
- PGT testing of the embryo(s) was performed and genetically normal embryos of both genders are available for transfer.
- You are eligible for family balancing here at AFC since you and/or your partner currently have at least one living child
- You prefer family balancing for a specific gender rather than transfer of best quality embryo

I/We authorize and consent to the thaw and transfer of:

- ☐ 1 (one) MALE (46XY) Embryo
- ☐ 1 (one) FEMALE (46XX) Embryo

I/We acknowledges that it may be necessary for AARL lab staff to thaw more than the specified number of embryos to have the desired number for transfer since not all embryos will survive the thaw process. I/We will allow the IVF team to thaw as many embryos as necessary in an attempt to reach my/our transfer goals.

Initials: ______ / ______

Assisted Hatching of Embryos

- ☐ I/We acknowledge that I/we have read about, understand, and consent to the use of Assisted Hatching of our embryos prior to embryo transfer.

- ☐ I/We DO NOT consent to Assisted Hatching under any circumstances: I/We acknowledge that this choice WILL have a significant negative impact on the success of the cycle.

Initials: ______ / ______
Notice of Arbitration

It is understood that any and all disputes relating to this Agreement or its breach, or to medical malpractice, that is, as to whether any medical services rendered under this contract were unnecessary or unauthorized or were improperly, negligently or incompetently rendered, shall be settled by arbitration in Scottsdale, Arizona (Maricopa County), in accordance with Arizona’s Revised Uniform Arbitration Act (A.R.S. §12-3001, et seq.), and utilizing the then-current procedural rules of the American Arbitration Association. I/We, by entering into this contract, are giving up my/our constitutional right to have any such dispute decided in a court of law before a jury, and instead are accepting the use of arbitration. Judgment upon the arbitration award may be entered in any court having jurisdiction hereof. The arbitrator or, if necessary, a court of competent jurisdiction, shall award the costs of arbitration, including reasonable attorneys’ fees, to AFC/AARL/AASC provided that any of them are the substantially prevailing party in the arbitration and/or in any subsequent litigation to enforce an arbitration award. Any arbitration shall be conducted in the English language and the award rendered in the United States dollars. Should I/we, or either of us, dismiss or abandon a claim or counterclaim before the arbitration hearing, AFC/AARL/AASC shall be deemed the “substantially prevailing party” for purposes of this section. Service of any petition to confirm the arbitration award shall be complete on personal delivery or the deposit of the petition and notice shall be served in the United States mail.

I/WE ACKNOWLEDGE THAT WE HAVE READ AND FULLY UNDERSTAND THIS INFORMED CONSENT/AGREEMENT IN ITS ENTIRETY. I/WE HAVE BEEN ENCOURAGED TO AND HAD THE OPPORTUNITY TO ASK QUESTIONS AND OUR QUESTIONS REGARDING THESE PROCEDURES HAVE BEEN ANSWERED TO MY/OUR COMPLETE SATISFACTION. I HAVE ALSO RECEIVED INFORMATION ABOUT ALTERNATIVE PROCEDURES TO ALLOW ME TO BECOME PREGNANT IF THEY EXIST. I/WE UNDERSTAND THAT I/WE MAY WITHDRAW CONSENT AT ANY TIME TO PARTICIPATE IN THIS PROGRAM, WITHOUT PREJUDICE.

I/We acknowledge that I/we have read and understood the information provided above regarding the Frozen Embryo Transfer process and its risks, and agree to go forward with this treatment as our signatures below testify.

If any clause, sentence, provision, or other portion of this Agreement is, or becomes illegal, null, void or unenforceable for any reason, or is held by any court of competent jurisdiction to be so, the remaining portions shall remain in full force and effect.

NOTICE: BY SIGNING THIS CONTRACT, YOU ARE AGREEING TO HAVE ANY ISSUE OF MEDICAL MALPRACTICE OR LEGAL ISSUE RELATED TO THIS AGREEMENT DECIDED BY NEUTRAL ARBITRATION, AND YOU ARE GIVING UP YOUR RIGHT TO A JURY OR COURT TRIAL.

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<th>Partner #1 (Print):</th>
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<td>Spouse/Partner #2 (Print):</td>
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