ARTIST

NOTE: THINGS IN BOLD AND/OR CAPS ARE THE BULLETS THAT WE WANT EMPHASIZED FROM THE BOXES IN THE CONSENT FORM – THESE SHOULD BE CONSTANTLY SHOWING ON THEIR RESPECTIVE PAGE

1. Techniques in IVF
   1. Core elements and their risks
      1. Medications
         1. **THE SUCCESS OF IVF LARGELY DEPENDS ON GROWING MULTIPLE EGGS AT ONCE**
         2. **INJECTIONS OF THE NATURAL HORMONES FSH AND/OR LH (GONADOTROPINS) ARE USED FOR THIS PURPOSE**
         3. **ADDITIONAL MEDICATIONS ARE USED TO PREVENT PREMATURE OVULATION**
         4. **AN OVRLY VIGOROUS RESPONSE CAN OCCUR, OR CONVERSELY AN INADEQUATE RESPONSE**
         5. **(add meds from new doc Maryam and I made)**
      2. Transvaginal Oocyte Retrieval
         1. **EGGS ARE REMOVED FROM THE OVARY WITH A NEEDLE UNDER ULTRASOUND GUIDANCE**
         2. **ANESTHESIA IS PROVIDED TO MAKE THIS COMFORTABLE**
         3. **INJURY AND INFECTION ARE RARE**
      3. IVF and Embryo Culture
         1. **SPERM AND EGGS ARE PLACED TOGETHER IN SPECIALIZED CONDITIONS (CULTURE MEDIA, CONTROLLED TEMPERATURE, HUMIDITY, AND LIGHT) IN HOPES OF FERTILIZATION**
         2. **CULTURE MEDIUM IS DESIGNED TO PERMIT NORMAL FERTILIZATION AND EARLY EMBRYO DEVELOPMENT, BUT THE CONTENT OF THE MEDIA IS NOT STANDARDIZED**
         3. **EMBRYO DEVELOPMENT IN THE LAB HELPS DISTINGUISH EMBRYOS WITH MORE POTENTIAL FROM THOSE WITH LESS OR NONE**
      4. Embryo Transfer
         1. **AFTER A FEW DAYS OF DEVELOPMENT, THE BEST APPEARING EMBRYOS ARE SELECTED FOR TRANSFER**
         2. **THE NUMBER CHOSEN INFLUENCES THE PREGNANCY RATE AND THE MULTIPLE PREGNANCY RATE**
         3. **A WOMAN’S AGE AND THE APPEARANCE OF THE DEVELOPING EMBRYO HAVE THE GREATEST INFLUENCES ON PREGNANCY OUTCOME**
         4. **EMRYOS ARE PLACED IN THE UTERINE CAVITY WITH A THIN TUBE**
         5. **EXCESS EMBRYOS OF SUFFICIENT QUALITY THAT ARE NOT TRANSFERRED CAN BE FROZEN**
         6. Recommendation charts (add in)
      5. Hormonal Support of Uterine Lining
         1. **Successful attachment of embryo(s) to the uterine lining depends on adequate hormonal support**
            1. **Progesterone**

**Administered by intramuscular or vaginal route for 2 to 10 weeks**

**Routinely prescribed**

* + - * 1. Estradiol

Administered by oral, vaginal, intramuscular or transdermal route for 2 to 10 weeks

Sometimes prescribed

* 1. Additional elements and their risks
     1. Intracytoplasmic Sperm Injection (ICSI)
        1. Purpose:
           1. **ICSI is used to increase the chance of fertilization when fertilization rates are anticipated to be lower than normal** due to male factor infertility (link to statements below)

Abnormal semen characteristics

Sperm problems (low count, poor motility, abnormal shape)

Congenital bilateral absence of the vas deferens (CBAVD)

Infertility caused by failure of the tubes connecting the testes to the penis to develop correctly

Associated with Cystic Fibrosis

Can be bypassed by aspirating sperm directly from the testicles or epididymis, and using them in IVF with ICSI to achieve fertilization

Non-obstructive azoospermia

Lack of sperm in ejaculate caused by failure of testes to produce sperm

* + - 1. Procedure:
         1. ICSI involves the direct injection of a single sperm into the interior of an egg using an extremely thin glass needle
      2. Birth Defect Risks:

The absolute risk is very low. This risk is mainly related to infertility factors rather than IVF procedure.

* + - 1. Genetic Related Risks:
         1. **An increased risk of genetic defects in offspring is reported**
         2. **ICSI will not improve oocyte defects**
         3. Sex Chromosome Abnormalities

Prevalence is slightly higher in children conceived via ICSI than is observed in the general IVF population (0.8% to 1.0% in ICSI offspring versus 0.2% in the general IVF population)

May reflect a direct paternal effect

* + - * 1. CBAVD and CF

Men with CBAVD are affected with a mild form of cystic fibrosis (CF), and this gene will be passed on to their offspring

* + 1. Assisted Hatching
       1. **ASSISTED HATCHING INVOLVES MAKING A HOLE IN THE OUTER SHELL (ZONA PELLUCID) THAT SUROUNDS THE EMBRYO**
       2. **HATCHING MAY MAKE IT EASIER FOR EMBRYOES TO ESPACE FROM THE SHELL WHICH SURROUNDS THEM**
    2. Embryo Disposition
       1. **FREEZING OF VIABLE EMBRYOS NOT TRANSFERRED AFTER EGG RETRIEVAL PROVIDES ADDITIONAL CHANGES FOR PREGNANCY**
       2. **FROZEN EMBRYOS DO NOT ALWAYS SURVIVE THE PROCESS OF FREEZING AND THAWING**
       3. **FREEZING EGGS BEFORE FERTILIZATION IS CURRENTLY LESS SUCCESSFUL THAN FREEZING OF FERTILIZED EGGS (EMBRYOS)**
       4. **ETHICAL AND LEGAL DILEMMAS CAN ARISE WHEN COUPLES SEPARATE OR DIVORCE; DISPOSITION AGREMENTS ARE ESSENTIAL**
       5. **IT IS THE RESPONSIBILITY OF EACH COUPLE WITH FROZEN EMBRYOES TO REMAIN IN CONTACT WITH ARI ON QUARTERLY BASIS**
       6. Cryopreservation
          1. Purpose:

Remaining oocytes or embryos following IVF may be frozen (or “cryopreserved”) for future use

* + - * 1. Summary of Indications:

To reduce the risks of multiple gestation

To preserve fertility potential in the face of certain necessary medical procedures

To increase the chance of having one or more pregnancies from a single cycle of ovarian stimulation

To minimize the medical risk and cost to the patient by decreasing the number of stimulated cycles and egg retrievals

To temporarily delay pregnancy and the risk of OHSS (link to OHSS)

* + - * 1. Risks:

Overall pregnancy rates at the national level with frozen embryos are lower than with fresh embryos.

Data do not indicate any likelihood that children born of embryos that have been cryopreserved and thawed will experience greater risk of abnormalities than those born of fresh embryos.

* + - 1. Legal Considerations
         1. Because of the possibility of you and/or your partner’s separation, death or incapacitation, it is important to decide on the disposition of any embryo(s), fresh or cryopreserved that remain in the laboratory. Since this is a rapidly evolving field, both medically and legally, ARI cannot guarantee what the available or acceptable avenues for disposition will be at any future date
         2. Alternatives:

Discarding the cryopreserved embryo(s)

Donating the cryopreserved embryo(s) for approved research studies

Donating the cryopreserved embryos to another couple in order to attempt pregnancy (You may be asked to undergo additional infectious disease testing and screening recommended by the FDA if you select this option.)

* + - * 1. Embryos are understood to be your property, with rights of surviorship. No use can be made of these embryos without the consent of both partners (if applicable)

In the event of divorce or dissolution of the marriage or partnership, the ownership and/or other rights to the embryo(s) will be as directed by the court decree and/or settlement agreement

In the event of the death or incapacitation of one partner, the embryo(s) will become the sole and exclusive property of the surviving partner

In the event of death or incapacitation of both partners or of a last surviving partner, the embryo(s) shall become the sole and exclusive property of ARI. In this event, I/we elect to: (please select and initial your choice)

**Insert chart**

1. Risks
   1. Risks to the Woman
      1. Ovarian Hyperstimulation Syndrome
         1. OHSS is the most serious side effect of ovarian stimulation
         2. Symptoms:
            1. Increased ovarian size
            2. Nausea and vomiting
            3. Accumulation of fluid in the abdomen
            4. Breathing difficulties
            5. Increased concentration of red blood cells
            6. Kidney and liver problems
            7. In the most severe cases, blood clots, kidney failure, or death (The severe cases affect only a very small percentage of women who undergo IVF—0.2 percent or less of all treatment cycles—and the very severe are an even smaller percentage)
         3. Occurs at two stages:
            1. Early - 1 to 5 days after your hGC-Orvidrel trigger
            2. Late – 10 to 15 days after your hCG-Orvidreal trigger as a result of the hCG (if pregnancy occurs)

The risk of severe complications is about 4 to 12 times higher if pregnancy occurs which is why sometimes hCG-Ovidrel trigger is withheld to reduce the possibility of this occurring.

* + 1. Cancer
       1. Many have worried that the use of fertility drugs could lead to an increased risk of cancer—in particular, breast, ovarian, and uterine (including endometrial) cancers. One must be careful in interpreting epidemiological studies of women taking fertility drugs, because all of these cancers are more common in women with infertility, so merely comparing women taking fertility drugs with women in the general population inevitably shows an increased incidence of cancer. **When the analysis takes into account the increased cancer risk due to infertility per se, the evidence does not support a relationship between fertility drugs and an increased prevalence of breast or ovarian cancer.**
    2. Risks of Pregnancy
       1. 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).
          1. **Insert table** (Potential risks in singleton IVF-conceived pregnancies)
          2. Key:

Absolute risk = % of IVF pregnancies in which the risk occurred

Relative risk = the risk in IVF versus the risk in non-IVF pregnancies

The numbers in parentheses (called the “Confidence Interval”) indicate the range in which the actual Relative Risk lies

* + - * 1. 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
      1. Multiple gestations
         1. 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
         2. Identical twinning occurs in 1.5% to 4.5% of IVF pregnancies
         3. IVF twins deliver on average three weeks earlier and weigh 1,000 gm less than IVF singletons.  Of note, IVF twins do as well as spontaneously conceived twins
         4. Triplet (and greater) pregnancies deliver before 32 weeks (7 months) in almost half of cases
      2. Abnormal Pregnancies
         1. Although embryos are transferred directly into the uterus with IVF, ectopic (tubal, cervical and abdominal) pregnancies as well as abnormal intra-uterine pregnancies have occurred either alone or concurrently with a normal intra-uterine pregnancy
         2. Termination of ectopic/abnormal pregnancy:

Methotrexate (a weak chemotherapy drug)

Side effects of methotrexate include nausea or vomiting, diarrhea, cramping, mouth ulcers, headache, skin rash, sensitivity to the sun and temporary abnormalities in liver function tests

Surgery

Risks of surgery include the risks of anesthesia, scar tissue formation inside the uterus, infection, bleeding and injury to any internal organs

* 1. Risks to Offspring
     1. Overall Risks
        1. **IVF babies may be at a slight increased risk for birth defects**
           1. 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
        2. **The risk for a multiple pregnancy [link to risks of multiple pregnancies] is higher for patients undergoing IVF, even when only one embryo is transferred.**
        3. **Multiple pregnancies are the *greatest risk* for babies following IVF**
        4. **Some risk may also stem from the underlying infertile state, or from IVF techniques or both**
        5. Singletons conceived with IVF tend to be born slightly earlier than naturally conceived babies (39.1 weeks as compared to 39.5 weeks)
        6. 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
     2. Birth Defects
        1. The rate of birth defects in IVF babies is 2.6-3.9% (versus 2-3% in the normal population). This difference is seen predominately in singleton males.
        2. Imprinting Disorders
        3. Childhood Cancers
           1. Most studies have not reported an increased risk
        4. Potential Risks in Singleton IVF Pregnancies
           1. **Insert table**
           2. Key:

Absolute risk = % of IVF Pregnancies in which the risk occurred

Relative Risk = the risk in IVF versus the risk in non-IVF pregnancies

The numbers in parentheses (called the “Confidence Interval”) indicate the range in which the actual Relative Risk lies

* + 1. Risks of Multiple Pregnancy
       1. Greatest risks:
          1. Preterm labor and delivery
          2. Pre-eclampsia
          3. Gestational diabetes
       2. Additional risks:
          1. Gall bladder problems
          2. Skin problems
          3. Excess weight gain
          4. Anemia
          5. Excessive nausea and vomiting
          6. Exacerbation of pregnancy-associated gastrointestinal symptoms including reflux and constipation
          7. Chronic back pain
          8. Intermittent heartburn
          9. Postpartum laxity of the abdominal wall
          10. Umbilical hernias
          11. Triplets and above increase risk to the mother of more significant complications including post-partum hemorrhage and transfusion
       3. Perinatal morbidity and mortality:
          1. Prematurity

Accounts for most of the excess perinatal morbidity and mortality associated with multiple gestations

Moreover, IVF pregnancies are associated with an increased risk of prematurity, independent of maternal age and fetal numbers

* + - * 1. Fetal growth problems and discordant growth among the fetuses
        2. Multifetal pregnancy reduction (where one or more fetuses are selectively terminated) reduces, but does not eliminate, the risk of these complications
        3. 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
        4. Vanishing twin

The death of one or more fetuses in a multiple gestation 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 or mother

* + - * 1. Shared placenta

Demise of a single fetus in a twin pregnancy after the first trimester is more common when they share a placenta, ranging in incidence from 0.5% to 6.8%, and may cause harm to the remaining fetus

Multiple fetuses (including twins) that share the same placenta have additional risks.

Twin-to-twin Transfusion Syndrome

A condition in which there is an imbalance of circulation between the fetuses

May occur in up to 20% of twins sharing a placenta

Excess or insufficient amniotic fluid may result from twin-to-twin transfusion syndrome.

Twins sharing the same placenta have a higher frequency of birth defects compared to pregnancies having two placentas

Twins sharing the same placenta appear to occur more frequently after blastocyst transfer

* + - 1. Complications:  
         1. Placenta previa and vasa previa are more common complications in multiple gestations
         2. Abruptio placenta also is more common and postpartum hemorrhage may complicate 12% of multifetal deliveries

* + - 1. Consequences:
         1. The major sequelae of prematurity

Cerebral palsy

Retinopathy of prematurity

Chronic lung disease

* + - * 1. The major sequelae of fetal growth restriction

Polycythemia – increased concentration of red blood cells in the blood

Hypoglycemia – low blood sugar

Necrotizing enterocolitis – death of gut tissue

* + - 1. Possible Additional Outcomes:
         1. 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
         2. 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
      2. Option of Selective Reduction
         1. Patients with more than twins are faced with the options of continuing the pregnancy with all risks previously described, terminating the entire pregnancy, or reducing the number of fetuses in an effort to decrease the risk of maternal and perinatal morbidity and mortality
         2. Multifetal pregnancy reduction (MFPR) decreases risks associated with preterm delivery, but often creates profound ethical dilemmas

Pregnancy loss is the main risk (1% to 5%)

* + - * 1. **Insert table**

1. Social/Legal
   1. Ethical and Religious Considerations in Infertility Treatment
      1. IVF involves creating human embryos outside the body
      2. IVF can involve the production of excess embryos and/or “high-order” multiple pregnancies (triplets +)
      3. We encourage patients and partners who desire to consult with their religious or ethical community for guidance on their treatment
   2. Psychosocial Effects of Infertility Treatment
      1. A diagnosis of infertility can be a devastating and life-altering event.
      2. Infertility and its treatment can affect a patient and her partner medically, financially, socially, emotionally and psychologically.
      3. Feelings of anxiousness, depression, isolation, and helplessness are not uncommon among patients undergoing treatment.
      4. Strained and stressful relations with partners and other loved ones are not uncommon as treatment progresses.
      5. Our healthcare team is available to address emotional and physical symptoms that can accompany infertility.
      6. In addition to working with our health care team to minimize emotional impacts, patients may consider working with mental health professionals specializing in infertility care.
      7. While it is normal to experience emotional ups and downs, it is important to recognize severe feelings.
      8. If you experience any of the following for a prolonged period of time, you may benefit from working with a mental health professional [LINK TO 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, Tel. 1-888-623-0744) or The American Fertility Association (AFA), (www.theafa.org, Tel: 1-888-917-3777).
2. loss of interest in usual activities
3. depression that doesn't lift
4. strained interpersonal relationships (with partner, family, friends and/or colleagues)
5. difficulty thinking of anything other than your infertility
6. high levels of anxiety
7. diminished ability to accomplish tasks
8. difficulty with concentration
9. change in your sleep patterns (difficulty falling asleep or staying asleep, early morning awakening, sleeping more than usual for you)
10. change in your appetite or weight (increase or decrease)
11. increased use of drugs or alcohol
12. thoughts about death or suicide
13. social isolation
14. persistent feelings of pessimism, guilt, or worthlessness
15. persistent feelings of bitterness or anger
    1. Legal Considerations to Offspring
       1. The law regarding embryo cryopreservation, thaw, parent-child status of any resulting child or children may be unsettled in the state in which the ART program is located
       2. ART Program does not give any legal advise
       3. You may consult a lawyer who is experienced in the area of reproductive law and embryo cryopreservation and disposition.
    2. Alternatives to IVF
       1. The following are placed into the fallopian tube directly:
          1. Gamete intrafallopian transfer (GIFT) – eggs and sperm
          2. Zygote intrafallopian transfer (ZIFT) – fertilized eggs
          3. Tubal embryo transfer (TET) – developing embryos
       2. Gametes (sperm and/or eggs) instead of embryos may be frozen for future attempts at pregnancy. This may also help to avoid future issues relating to disposition of any cryopreserved embryos.
    3. 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 of 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 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.

In addition, ARI physicians and scientists may include information about IVF procedures in medical publications and professional presentations. In these publications and presentations the identities of the patients involved in the IVF procedure remain confidential. ARI keeps patient medical records and information confidential through standard procedures for the protection of patient identities.

* 1. Financial

I/We have had a financial consult and have been given a copy of our benefits from the insurance cards we provided to ARI. I/We have been encouraged to check our own benefits. I/We are personally financially responsible for the expense of this treatment and any additional expenses for the medical problems or those for a child. Expenses for IVF treatment consist of the cost of the medications, laboratory, facility and professional fees. All questions have been answered to my/our satisfaction prior to starting treatment.