

**Island Reproductive Services**

**www.islandreproductive.com**

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**Informed Consent for Assisted Reproduction:**

**In Vitro Fertilization (IVF)  
Intracytoplasmic Sperm Injection (ICSI)  
Assisted Hatching  
Embryo Freezing**

Your IVF cycle is being performed by your physician(s) at Island Reproductive Services, PC in conjunction with the laboratory at Reproductive Center of Central New Jersey (RCCNJ).

Please place your initials below to indicate which components of IVF treatment you agree to undertake in your upcoming treatment cycle. Also, initial each page to indicate that you have read and understand the information provided. If you do not understand the information provided, please speak with your treating physician. There are a few locations within the consent form where you are being asked to make a decision. Please initial your choice and sign where requested.

**Chosen Elements of Treatment:**

Signatures:

Patient	Partner (if applicable)	Date	Treatment
_____	_____	_____	<b>In-Vitro Fertilization</b> (Including egg retrieval and embryo transfer)
_____	_____	_____	<b>Intracytoplasmic Sperm Injection</b>
_____	_____	_____	<b>Assisted Hatching</b>
_____	_____	_____	<b>Embryo Cryopreservation (Freezing)</b>

Physician \_\_\_\_\_ Date \_\_\_\_\_  
Witness \_\_\_\_\_ Date \_\_\_\_\_

Initials: Patient \_\_\_\_\_ Partner (if Applicable): \_\_\_\_\_

## OVERVIEW

In Vitro Fertilization (IVF) is an elective therapy which has become an established treatment for many forms of infertility. The main goal of IVF is to help a patient become pregnant using her own eggs and sperm from her partner (or from a donor). This consent reviews the IVF process from start to finish. It includes a summary of the risks that this treatment may pose to you and/or your offspring. While best efforts have been made to disclose all known risks, there may be risks of IVF which are not yet known at the time of this writing.

An IVF cycle typically includes the following steps and/or procedures:

- Medications to grow multiple eggs
- Retrieval of eggs from your ovaries
- Insemination of eggs with sperm
- Culture of any resulting fertilized eggs (embryos)
- Placement (transfer) of one or more embryos into the uterus
- Support of the body with hormones to help permit and sustain pregnancy

In certain cases, these additional procedures may be used:

- Intracytoplasmic sperm injection (ICSI) to increase the chance of fertilization
- Assisted hatching of embryos to increase the chance of embryo attachment (implantation)
- Embryo cryopreservation (freezing)

### 1. TECHNIQUE OF IVF

#### A. Medications for IVF Treatment

- The success of IVF largely depends on growing multiple follicles
- Injections of the hormones FSH and/or LH (gonadotropins) are used for this purpose
- Additional medications are used to prevent premature ovulation
- An inadequate response as well as an over vigorous response can occur to medications

Medications may include, but are not limited to, the following:

#### ***Gonadotropins or injectable “fertility drugs” (Follistim<sup>®</sup>, Gonal-F<sup>®</sup>, Bravelle<sup>®</sup>, Menopur<sup>®</sup>):***

These naturally occurring hormones stimulate the ovary to hopefully grow multiple eggs over the span of 1-2 weeks. All of these medications contain FSH (follicle stimulating hormone) to stimulate growth of your follicles (which contain eggs). Some medications also contain LH (luteinizing hormone) that works with FSH to mature your eggs and produce hormones such as estrogen. These medications are self administered by subcutaneous or intramuscular injection. Proper dosage of these medications and the timing of egg retrieval require monitoring of your response by blood tests and ultrasound examinations while you use these medications.

As with all injectable medications, bruising, redness, swelling, or discomfort can occur at the injection site. Rarely, patients have an allergic reaction to these medications. Many women experience some bloating and mild discomfort as the ovaries becomes temporarily enlarged from the growth of multiple follicles. Up to 2% of women will experience ovarian hyperstimulation syndrome (OHSS) (see full discussion in the risks to women section which follows). Other risks and side effects of gonadotropins include, but are not limited to, fatigue, headaches, temporary weight gain, mood swings, nausea, and clots in blood vessels.

Your physician will assess the ability of your ovaries to respond to medication prior to treatment. However, it is possible that stimulation may result in few follicles developing, the end result being few or no eggs obtained at egg retrieval or even cancellation of the cycle prior to egg retrieval.

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Some older research suggested that the risk of ovarian cancer may increase in women who take fertility medications over a long period of time. This risk was eliminated in women who became pregnant at any time in their life. These studies had significant flaws which limited the strengths of their conclusions. More recent studies have not confirmed this risk at all. Infertility (and never becoming pregnant) in general is a risk factor for ovarian cancer and may have contributed to the falsely attributed risk of tumors. There has also been a question of whether these medications could increase your risk of breast or uterine cancer. At this time, there is no consistent or reliable evidence to show this to be the case.

**GnRH-agonists (leuprolide acetate, Lupron®):** This medication is taken by subcutaneous injection to prevent your ovulation (release of eggs) from occurring too early. Although this is an FDA (U.S. Food and Drug Administration) approved medication, it has not been approved for use in IVF, although it is routinely used for that purpose. Potential side effects include hot flashes, vaginal dryness, bone loss (long term use), muscle aches, nausea, vomiting, and local skin reactions at the injection site. No serious side effects are known. Since this medication is often started after ovulation, it is possible that it will be taken in an early pregnancy. Although this has no known association with any fetal malformations and is unlikely to occur, you should use barrier contraception (condoms) during this time.

**GnRH-antagonists (Ganirelix acetate or cetrorelix acetate – Antagon®, Cetrotide®):** This is another class of medication to prevent ovulation. They are used for a shorter time period usually at the end of your stimulation. Potential side effects include, but are not limited to, abdominal pain, headaches, skin reaction at the injection site, and nausea.

**Human chorionic gonadotropin (hCG - Profasi®, Novarel®, Pregnyl®, Ovidrel®):** This is a hormone used in IVF to induce final maturation of the eggs and ovulation. The timing of this medication is critical. Potential side effects are breast tenderness, bloating, and pelvic discomfort.

**Progesterone and/or Estradiol:** These are hormones normally produced by your ovaries to support a pregnancy. After egg retrieval some ovaries will not produce adequate amounts of these hormones to support pregnancy. Therefore hormonal support given by injection, oral medication (Prometrium®), or vaginal medication (Crinone®, Endometrin®, Prochieve®). This is discontinued later in pregnancy. These medications have not been associated with any fetal anomalies. Side effects may include sleepiness, depression, nausea, risk of blood clot, or local allergic reaction if given by injection.

**Oral Contraceptive Pills (birth control pills):** Some treatment protocols include these medications prior to beginning gonadotropin injections in order to suppress ovulation or to schedule a menstrual period. Side effects include unscheduled bleeding, headache, breast tenderness, nausea, and risk of blood clot or stroke.

**Other medications:** Antibiotics may be given around the time of the egg retrieval and embryo transfer. These may be associated with allergic reactions, yeast infection, nausea, diarrhea, rashes, and sensitivity to sunlight. Steroids, heparin, or aspirin may be included in your treatment protocol on an individualized basis.

#### B. Transvaginal Oocyte (Egg) Retrieval

Oocyte retrieval is the removal of eggs from the ovary. A vaginal ultrasound probe is used to visualize the ovaries while you are asleep and a long, thin needle is guided into each follicle to remove the eggs and hormone producing cells. Rarely the ovaries are not accessible by vaginal route and an abdominal (though the belly) approach is needed. This is generally a very safe procedure, but risks include:

- Infection: Bacteria are normally present in the vagina and may be accidentally transferred into the belly through the needle. This could cause infections of the uterus, fallopian tubes, ovaries, or other

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organs. The estimated incidence of infection is much less than 1%. Treatment could require the use of oral or intravenous antibiotics, and in very rare cases, hospitalization or surgery. Antibiotics are given preventatively starting before your egg retrieval. However, there is no way to eliminate all risk.

- Bleeding: the needle passes through the vagina into the ovary, next to blood vessels. A small amount of blood loss is common during the procedure, but major bleeding is estimated to occur in less than 0.1% of cases. In the event of major bleeding, a blood transfusion or surgery may be required.
- Trauma: Despite ultrasound guidance, it is possible to damage nearby organs, including the bladder, bowel, appendix, ovaries, or ureters, requiring additional treatment or surgical repair. This risk is exceedingly rare.
- Anesthesia: the use of anesthesia during the egg retrieval can produce unintended complications such as an allergic reaction, low blood pressure, nausea, vomiting, and even death in very rare cases.
- Failure: it is possible no eggs will be retrieved, or that the eggs may be immature or of poor quality, through no fault of the physician performing the procedure or monitoring your cycle.

### C. IVF and Embryo Development

After eggs are retrieved, they are brought to the embryology laboratory where they are grown in specialized conditions. They are placed in small dishes with culture medium, or specialized fluid to support development of the embryos made to mimic the body's fluid. These dishes are stored in incubators and periodically checked for growth and development. A few hours after the eggs are retrieved, sperm are placed in culture medium with the eggs, or individual sperm are injected into each mature egg in a technique called intracytoplasmic sperm injection (ICSI). The eggs are then returned to the incubator.

The following day and every day thereafter, the dishes are checked for signs of fertilization and growth. Normal development at this stage is evident by a single cell (zygote). Normally, embryos grow to about 8 cells 3 days following egg retrieval. Embryos are normally at the blastocyst stage 5 days after egg retrieval with more than 80 cells and an inner fluid filled cavity.

It is important to note that since many eggs and embryos are abnormal, not all eggs will fertilize and not all embryos will grow. Embryos that grow normally have a better chance of producing a pregnancy. Not all embryos that appear to grow normally are genetically normal. Appearance of embryos is difficult to measure and is not a perfect assessment but is the best tool to guide embryos for embryo transfer.

In spite of all reasonable precautions, any of the following may occur in the laboratory that would prevent the establishment of a pregnancy:

- Fertilization of the eggs may fail to occur
- Eggs may fertilize abnormally and not be available to use, or fertilized eggs may fail to grow
- Contamination or a laboratory accident may result in loss or damage to some / all eggs or embryos
- Laboratory equipment may fail, and/or extended power loss can occur which could lead to the destruction of eggs, sperm, or embryos
- Other unforeseen circumstances may prevent any step of the process
- Natural disasters or security emergency or terrorist acts could destroy the laboratory or its contents, including any sperm, eggs or embryos being stored there

Quality control in the laboratory is extremely important. Sometimes immature or unfertilized eggs, sperm, or abnormal embryos (either abnormally formed or degenerating) that would routinely be discarded can be used for quality control. You are being asked to allow the clinic to use this material for quality control purposes before being discarded in accordance with normal laboratory procedures / applicable laws. None of this

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material will be used to establish a pregnancy or a cell unless you sign other consent forms to allow that. Please indicate your choice below:

____ I/We hereby <b>CONSENT</b> to allow the laboratory to use my/our immature, unfertilized eggs, left-over sperm, or abnormal embryos for quality control and training purposes before they are discarded		
Patient	Partner	Date
_____	_____	____/____/____

____ I/We hereby <b>DO NOT CONSENT</b> to allow the laboratory to use my/our immature, unfertilized eggs, left-over sperm, or abnormal embryos for quality control and training purposes before they are discarded		
Patient	Partner	Date
_____	_____	____/____/____

D. Embryo Transfer

After being allowed to grow in the laboratory for a few days, one or more embryos are selected to place back inside the uterine cavity (embryo transfer). The embryo transfer is done with a small catheter which is a thin, flexible, tube. Ultrasound guidance is often used to direct the catheter to the best place. Complications from embryo transfer are exceedingly rare, but can include infection or damage to the embryo(s).

The pregnancy rate and risk of multiple pregnancies are related to the number of embryos transferred. A woman's age and the quality of the embryos have a significant effect on the pregnancy rate and the risk of miscarriage. It is possible to develop more pregnancies than the number of embryos placed, but this is uncommon (1%). The number of embryos transferred will be discussed between you and your physician in accordance with national guidelines set forth by the American Society for Reproductive Medicine (ASRM). These limit the number of embryos transferred based on stage of embryo development, embryo quality, age, and a patient's personal history. In some cases, embryos will stop growing and will be discarded. In other cases embryos will continue to grow but may not be of a high enough quality to freeze. Some patients will have high quality embryos not transferred to freeze and this possibility should be discussed with your physician.

E. Hormonal Support

Successful attachment of the embryos to the uterine lining depends at least partially on the hormonal support of the body. The hormone progesterone and estrogen help accomplish this. Normally the ovary makes adequate amounts of these hormones, although this varies between women. During IVF cycles, hormonal support may not be adequate due to medications during the cycle or due to the egg retrieval. Progesterone is routinely given by oral, vaginal, or intramuscular route. In some cases, estrogen pills may also be given. This support may be given for up to 12 weeks in pregnancy.

F. Intracytoplasmic Sperm Injection (ICSI)

ICSI provides an effective treatment for male factor infertility, especially more severe forms. With ICSI, individual sperm are placed inside an egg, as opposed to allowing eggs and sperm to mix on their own with traditional IVF. This can overcome difficulty in sperm penetrating the outer, thick covering of the egg. ICSI can help with, but does not guarantee, fertilization (unification of the egg and sperm). Additionally, ICSI does not

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guarantee that the embryos will grow normally or implant. ICSI can be used with sperm samples given normally by ejaculation, frozen samples, or with techniques whereby sperm is collected surgically from the epididymis or testicle.

Long term reports on the potential risk of birth defects associated with ICSI, in comparison to IVF alone, have shown conflicting results. Some reports have suggested that ICSI may result in an increased risk of certain major congenital anomalies. If this is true, it is not known whether the risk occurs as a result of the ICSI process itself or due to inherent problems with the sperm. The overall risk of major birth defects in the U.S. population is between 2-3%, and some studies show ICSI may increase this risk to approximately 4%. Studies have also tried to assess whether ICSI increase any risk of intellectual and motor development. These studies are extremely difficult to perform and have also produced mixed results.

Sex chromosome abnormalities (X and Y chromosome) in children born by ICSI seem to be higher than children born by IVF alone. The increase in risk is very small (0.8-1 % versus 0.2%). Again, this risk may be due to the ICSI procedure or due to the sperm itself. Men who have low sperm counts and other problems on semen analysis are themselves at increased risk for having sex chromosome abnormalities that may be passed onto a child and/or affect a pregnancy.

Some men do not produce sperm in sufficient quantities to show up in a semen analysis. A number of reasons may be responsible for this including radiation, chemotherapy, surgery on the tests, or undescended testicles. Genetic reasons may sometimes account for this as well. In some men enough sperm may be extracted directly from the testicle or epididymis. Again, if genetic abnormalities (including y-chromosome micro-deletions) are present in the man these may be passed onto children and a full discussion should take place with your physician prior to considering therapy.

#### G. Embryo Hatching

In an early embryo, the cells composing the embryo are surrounded by an outer membrane (zona pellucida). Normally, a part of this membrane naturally dissolves, allowing the embryo cells to escape and implant. Hatching is required for this process to occur.

In the laboratory, an embryologist has the ability to assist this hatching process by making an opening in the outer membrane of the embryo. This can be done by one of several techniques. This may potentially improve pregnancy rates, but here is no guarantee. Theoretically, this may cause damage to the embryo resulting in loss of some cells or death of the embryo. Assisted hatching may also increase the risk of identical twinning which can be a more complicated pregnancy. It is possible that other, unknown risks may occur.

#### H. Embryo Cryopreservation

Freezing embryos (cryopreservation) is a common procedure. Often more embryos are produced during your cycle of IVF than are transferred into the uterus. If these embryos continue to grow and are of sufficient quality, they may be frozen. They can be used in the future if the initial embryo transfer does not result in pregnancy, for an additional pregnancy in the future, to lower multiple pregnancy risk by transferring fewer embryos, or to make embryo transfer safer in patients who have severe ovarian hyperstimulation syndrome and who may become sick if they undergo a fresh embryo transfer. Additionally, patients worried about their future fertility potential (for instance those undergoing chemotherapy) may elect to undergo IVF with embryo cryopreservation for the future. Pregnancy rates for frozen embryos vary between patients and practices. Overall they are lower than pregnancy rates from fresh cycles. This may be the result of the freezing process. Often embryos frozen are not the best embryos produced since the best embryos are often transferred, and this may affect pregnancy rates.

There are several techniques used for embryo cryopreservation. Our practice uses a rapid freezing technique called vitrification that seems to cause much less damage to embryos. Although the chance that any single embryo will survive the freezing and thawing technique is very high, there is no guarantee that the embryo will be viable for use or will produce a pregnancy. Theoretically this process could damage an embryo but the data we have at this time does not show this to be the case. At this time there is no indication that children born as a result of frozen embryos have higher rates of abnormalities of any kind compared to fresh embryos.

It is important to make decisions in advance regarding the future use of embryos in your possession. It is possible that you and your partner through separation, incapacitation, or death, may in possession of remaining embryos. Island Reproductive Service and its physicians cannot guarantee the federal, state, or local laws for disposition of such embryos at any given time and therefore we urge you to consider the disposition of any remaining fresh or frozen embryos. In addition to your own personal use, other alternatives are:

- Discarding the embryo(s)
- Donating the embryo(s) for approved research
- Donating the embryo(s) to another couple in order that they attempt to achieve pregnancy. In this case you and your partner may be asked to undergo additional blood work and /or screening as recommended by the Federal Food and Drug Administration (FDA)

Embryos are considered to be your legal property, with survivorship rights. Your consent is required for any use of these embryos. In the event of divorce or dissolution of your marriage or partnership, the ownership and any rights to the embryos will be as directed by court decree and/or settlement agreement and/or any other relevant federal, state, or local laws. In the event of death or incapacitation of one partner, the embryo(s) will become the sole and exclusive property of the surviving partner, unless otherwise previously agree to legally.

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

	Patient	Partner
1. Thaw and discard the embryo(s):	_____	_____
2. Donate the embryo(s) for research:	_____	_____
3. Donate the embryo(s) to Island Reproductive Services, PC, for the use of another couple	_____	_____

Cryopreserved Embryo Storage

Island reproductive Service, PC in conjunction with Reproductive Center of Central New Jersey (RCCNJ) will cryopreserve (freeze) embryos with your consent and with your understanding of the financial commitment both initially and ongoing to that process. With your consent, at any time frozen embryos can be thawed and transferred (if appropriate), donated to research, to Island reproductive Service, PC/RCCNJ, or to another couple directly, discarded, transferred to another storage facility.

Freezing and maintaining embryos is labor intensive and expensive. You will be charged both an initial freezing fee as well as yearly fees for maintaining frozen embryos. Your physician(s) will inform you as to the exact amount of these fees. Patients/couples who have frozen embryo(s) must remain in contact with Island reproductive Service, PC/RCCNJ on an annual basis to inform us of your wishes and to pay any and all fees associated with storage of the embryo(s).

Initials: Patient \_\_\_\_\_ Partner (if Applicable): \_\_\_\_\_

If Island reproductive Service, PC/RCCNJ has not heard from you for any reason for a period of 2 (two) years **OR** if Island reproductive Services, PC/RCCNJ has not received the appropriate fees for continued embryo storage for any reason for 2 (two) years **AND** Island reproductive Service, PC/RCCNJ is unable to contact you after reasonable, documented efforts have been made (including but not limited to certified letter to the last known address on file for you or by telephone call to the last listed phone number for you), the embryo(s) will be considered to be abandoned. In this case, the embryo(s) will then be considered the property of Island reproductive Services, PC/RCCNJ and may be destroyed by Island reproductive Services, PC/RCCNJ in accordance with normal laboratory procedures and applicable law.

It is additionally possible that embryos donated by you for research, to Island reproductive Services, PC/RCCNJ for another couple's use, or to another couple directly for their use may not be able to be used in a timely fashion or may be restricted by law. While every effort will be made to abide by your wishes, no guarantees can be given that embryo(s) will be used for their intended purpose. In this circumstance, if after 3 (three) years no recipient or research project can be found, or your embryos for any reason are not eligible, your embryo(s) will be discarded by Island reproductive Services, PC/RCCNJ in accordance with laboratory procedures and applicable laws.

## **2. RISKS TO THE WOMAN**

### **A. Ovarian Hyperstimulation Syndrome (OHSS)**

During your IVF cycle, you will take medications to increase the number of eggs produced during that month. Your physician will monitor you to make sure your response is adequate but not too high. When you produce too many eggs and/or your hormone values are too high, you may have OHSS. Some women get OHSS despite having fewer eggs or lower hormone values. OHSS has a wide range of severity from very mild to severe in nature. Mild symptoms can include bloating, abdominal cramping, and mild nausea due to the increased size of your ovaries and/or higher hormone values. If the OHSS becomes more severe, you may leak fluid into your abdomen and even into your lungs, causing more severe pain and potentially some difficulty breathing. You may become dehydrated and notice decreased urination or a darker color urine. You may experience vomiting or dizziness. In severe case, your vital organs such as your liver and kidneys can become injured. You may be at a higher risk of having a life threatening blood clot and even at risk for death.

Symptoms, if present, typically occur at one of two different times: either in the week following your shot of hCG to trigger ovulation or if you are pregnant following embryo transfer. Less than 1% of women experience of severe form of OHSS. Your physician(s) will monitor you during your cycle for this.

It is not possible to predict with certainty which woman will experience OHSS. Your physician(s) may make recommendations to you at any time regarding your risk for OHSS and may recommend treatment modifications including, but not limited to, cancelling your cycle at any time, cancelling your egg retrieval, limiting the number of embryos transferred, or freezing all your embryos and delaying embryo transfer.

### **B. Pregnancy**

In general, all pregnant women have risks in pregnancy. Those include risks of exacerbating an underlying medical condition, developing a pregnancy induced medical condition, and risks of complications related to delivery of a baby. These risks may be life threatening.

Pregnancies that occur with IVF may be associated with increased risks of certain conditions such as pregnancy induced high blood pressure (preeclampsia), abnormal implantation of the placenta (previa and/or accreta), premature separation of the placenta (abruption), diabetes, and need for cesarean delivery. This list is not all

inclusive. Some of this increase in risk may be related to the age or cause for infertility in the woman undergoing treatment. It is also possible that the IVF procedure itself is the cause for some of this risk. Assigning the relative contribution of each cause is very difficult. Overall, these risks are still small.

Approximately 30% of all IVF pregnancies result in multiple pregnancies. The result is most often twins but high order multiples (triplets or more) can occur. Identical twinning can also occur with a higher frequency. As a result, many IVF pregnancies result in children born before their due date. Twins deliver an average of 3 (three) weeks early and high order multiples deliver even earlier. It should be noted that IVF twins deliver at a comparable time to natural twins. There is a procedure termed fetal reduction to reduce the number of pregnancies. This can be discussed with your physician if necessary with appropriate counseling.

While embryos are transferred directly into the uterus with IVF, it is possible to develop a pregnancy outside the uterus called an ectopic pregnancy, which is most often but not always located in a fallopian tube. Occasionally, an ectopic pregnancy may coexist with an intrauterine pregnancy, called a heterotopic pregnancy. Pregnancies outside the uterus are not normal, do not develop into an ongoing pregnancy, and are life threatening for the woman. They can be treated medically with methotrexate (a chemotherapeutic medication) or by surgery. Treatment is individualized for each patient when it is necessary. Each treatment entails a specific set of risks.

### **3. RISKS TO THE OFFSPRING**

#### **A. Overall risks**

Millions of children have been born worldwide following IVF treatments since it was made available in 1978. Many studies have tried to assess the health of children born after IVF. Additional treatment with ICSI has been available since 1992. Some studies have questioned whether overall risks to children born from IVF and/or ICSI are equivalent to children conceived naturally. This area of research is very difficult to conduct. It is very difficult to compare patient groups since the comparison group is not all women but women with infertility. Even those studies that show increased overall risks show that increase to be very small.

#### **B. Birth Defects**

As discussed earlier, the overall risk of birth defects is 2-3%. This risk may be slightly higher, up to 4%, in children born through IVF. For unknown reasons, this risk seems to be seen mostly in singleton males. Studies are unable to link IVF with any particular birth defect. Certain rare disorders, called imprinting disorders, are related to the regulation of genes in the body, and whether the genes are regulated by the maternal or paternal gene. Some studies, but certainly not all, have found an increased risk of certain imprinting disorders such as Beckwith-Weiderman Syndrome, in children born through IVF. There is no reliable research to show that children born through IVF and/or ICSI are at higher risk for childhood cancers.

Studies of the long-term development of children born through IVF have generally been reassuring. These studies are exceedingly difficult to perform and interpret. Some studies have shown a slightly higher risk of cerebral palsy and developmental delay, but most of this seemed to be the results of prematurity and consequences of multiple pregnancies.

#### **C. Multiple Pregnancy**

Initials: Patient \_\_\_\_\_ Partner (if Applicable): \_\_\_\_\_

Maternal complications associated with multiple pregnancies include, but are not limited to, preterm labor, preeclampsia, diabetes, cesarean delivery, and placental problems as discussed earlier. Other problems can include anemia, excess weight gain, excessive nausea and vomiting, gastric reflux and constipation, back pain, hernias, and skin problems. Bleeding at or after the time of delivery is also increased with multiple pregnancies. IVF is associated, regardless of the age of the mother or the timing of delivery, with increased risks of prematurity. These include problems with growth. Fetal reduction reduces but does not eliminate these risks.

The death of a fetus is increased with multiple pregnancies and increases with each additional pregnancy. However, the overall risk is exceedingly low, <0.5% for singletons, 1% for twins, and 2% for triplets. This number is changing all the time with improved neonatal care.

Multiple pregnancies that share the same placenta have a high rate of complications that can include death to one or more fetuses, growth differences, and amniotic fluid differences. A particular problem called twin-twin transfusion syndrome can occur which requires frequent monitoring and treatment. Twins that share placentas are most common after IVF, although the risk is still very low.

Placental problems, whether premature separation (abruption), a low placenta (previa), or one that sticks inside the uterus after delivery (accrete) are more common with multiple pregnancies. This can increase a woman's risk of bleeding, blood transfusion, surgery, or death in pregnancy. Fetal risks with growth and death may increase as a consequence. It is unclear whether IVF or just multiple pregnancy increases these risks.

Selective reduction: Pregnancies with more than 2 fetuses have an excessive amount of increased risks for both the mother and the babies. The risks become higher with each additional fetus. You should consider your own personal beliefs prior to determining how many embryos are transferred. Patients with high order pregnancies are faced with continuing a dangerous pregnancy, terminating an entire pregnancy, or selectively reducing one or more fetuses. This procedure can drastically reduce but not eliminate all risks. The main risk of this procedure is pregnancy loss of the entire pregnancy. Your physician can provide you with more information if necessary.

#### **4. Ethical/Religious Concerns**

We realize that due to personal, moral, religious and/or other beliefs that certain treatments or certain parts of treatment may not be appropriate for every patient. At any time in the counseling and treatment process you should feel free to express your own personal concerns with your physician free of judgment. The quality of your care will not be altered in any way, except by restrictions that you may place on yourself. We encourage you to consult with any religious or ethics advisor you feel is necessary.

#### **5. Psychosocial Risks**

The process of undergoing fertility treatment itself is stressful. It can affect a patient's life in many ways, including financially, emotionally, medically, and psychologically. The process contributes to anxiety, can cause depression, feelings of inadequacy, and loneliness for both partners. Personal and intimate relationships can even be affected at any time in the process. If we feel you would benefit or if you feel you would benefit from psychological counseling we would be happy to assist you at any time. We may also recommend adjunctive therapies for stress reduction.

If you experience prolonged feelings of depression, anxiety, change in sleep and personal habits, unusual weight loss, or extremely high levels of stress please let us know. You may benefit from working with a mental health professional.

Initials: Patient \_\_\_\_\_

Partner (if Applicable): \_\_\_\_\_

National support groups can also provide guidance. RESOLVE [www.resolve.org](http://www.resolve.org) (703) 556-7172 as well as the American Fertility Association [www.theafa.org](http://www.theafa.org) (888) 917-3777 can provide other resources and support.

**6. Alternatives to IVF**

Other forms of treatment exist for infertility depending on the individual(s) involved and the diagnosis(es). These may include such treatments as inseminations, donor eggs, sperm, or embryos, gamete intra-fallopian tube transfer (GIFT), zygote intra-fallopian tube transfer (ZIFT), and surgical therapies. Other forms of therapy have either been attempted by me/us or else have been explained and offered, to the extent that my medical diagnosis makes each individual therapy an option.

**7. Legal Considerations and legal counseling**

Current laws are not necessarily an indication of future regulation in the area of fertility and IVF. Specifically laws concerning cryopreservation of eggs and embryos, their future thaw and use, the disposition of extra embryos or eggs, parental rights, and any other aspect of treatment are subject to national, state, and local changes in statutes. We acknowledge that neither Island reproductive Services, PC nor RCCNJ, nor any of its physicians or representatives, has given us legal advice and that any legal advice required we have sought out ourselves. We have been informed that we may wish to consult with a lawyer with expertise in this field for any concerns or questions we may have.

I/we do hereby release and hold harmless Island reproductive Services, PC and RCCNJ, and any and all of their employees, from any liabilities arising from problems due to ovarian stimulation with medications, egg retrieval, embryo transfer, pregnancy complications, problems arising in any offspring achieved through IVF and related treatments, and any and all aspects of the IVF treatment process. I/we hereby acknowledge that my physician(s) has fully explained to me the purpose and alternatives of the procedure and has discussed the risks of the treatment. I/we have been given an opportunity to ask questions and all of my/our questions have been answered fully and satisfactorily. I /we acknowledge that no guarantees or assurances have been made to me/us concerning the outcome of the treatment. I/We understand the above consent form. All of our questions about the above treatment have been answered.

**Patient**

_____ Signature	_____ Printed Name	_____ Date
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**Partner**

_____ Signature	_____ Printed Name	_____ Date
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**Witness**

_____ Signature	_____ Printed Name	_____ Date
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