

PATIENT NAME: _____

RECORD #: _____



THE CENTER FOR HUMAN REPRODUCTION (CHR)

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Informed Consent for Assisted Reproduction: In Vitro Fertilization, Intracytoplasmic Sperm Injection, Assisted Hatching, Embryo Cryopreservation, Affirmation of Sexual Intimacy, Administration of Fertility Enhancing Medications

Adopted on: 2/6/2014

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: _____ Date: _____

Physician / Witness: _____ Date: _____

Option

In Vitro Fertilization

(includes egg retrieval and embryo transfer)

Intracytoplasmic Sperm Injection

(or "ICSI")

Assisted Hatching

Embryo Cryopreservation

(requires completion of Disposition of Embryos statement)

Patient initial

Partner initial

Process, Risk, and Consent

In Vitro Fertilization (IVF) has become an established treatment for many forms of infertility. The main goal of IVF is to allow a patient the opportunity to become pregnant using her own eggs or donor eggs and sperm from her partner or from a donor. This is an elective procedure designed to result in the patient's pregnancy when other treatments have failed or are not appropriate.

This consent reviews the IVF process from start to finish, including the 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 of IVF that are not yet clarified or even suspected at the time of this writing.

An IVF cycle typically includes the following steps or procedures:

- Medications to grow multiple eggs
- Retrieval of eggs from the ovary or ovaries
- Insemination of eggs with sperm
- Culture of any resulting fertilized eggs (embryos)
- Placement ("transfer") of one or more embryo(s) into the uterus
- Support of the uterine lining with hormones to permit and sustain pregnancy

In certain cases, these additional procedures can be employed:

- Intracytoplasmic sperm injection (ICSI) to increase the chance for fertilization
- Assisted hatching of embryos to potentially increase the chance of embryo attachment ("implantation")
- Cryopreservation (freezing) of eggs or embryos

Note: At various points in this document, rates are given which reflect what are believed to be U.S. national averages for those employing IVF treatments. These include items such as pregnancy rates, Cesarean delivery rates, and preterm delivery rates. These rates are not meant to indicate the rates of these outcomes within individual practices offering IVF, and are not to be understood as such. Individual practices may have higher or lower pregnancy and delivery rates than these national averages, and also higher or lower risks for certain complications. It is appropriate to ask the practice about their specific rates.

Also note that while this information is believed to be up to date at the time of publication (2013), newer reports may not yet be incorporated into this document.

IVF Procedures

Medications for IVF Treatment

- **The success of IVF largely depends on growing multiple eggs at once.**
- **Injections of the natural hormones FSH and/or LH (gonadotropins) are used for this purpose.**
- **Additional medications are used to prevent premature ovulation.**
- **An overly vigorous ovarian response can occur, or conversely an inadequate response.**

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

- **Gonadotropins, or injectable “fertility drugs”** (Follistim®, Gonal-F®, Bravelle®, Menopur®): These natural hormones stimulate the ovary in hopes of inducing the simultaneous growth of several oocytes (eggs) over the span of 8 or more days. All injectable fertility drugs have FSH (follicle stimulating hormone), a hormone that will stimulate the growth of your ovarian follicles (which contain the eggs). Some of them also contain LH (luteinizing hormone) or LH-like activity. LH is a hormone that may work with FSH to increase the production of estrogen and growth of the follicles. Low-dose hCG (human chorionic gonadotropin) can be used in lieu of LH. These medications are given by subcutaneous or intramuscular injection. Proper dosage of these drugs and the timing of egg recovery require monitoring of the ovarian response, usually by way of blood tests and ultrasound examinations during the ovarian stimulation.

As with all injectable medications, bruising, redness, swelling, or discomfort can occur at the injection site. Rarely, there can be an allergic reaction to these drugs. The intent of giving these medications is to mature multiple follicles, and many women experience some bloating and minor discomfort as the follicles grow and the ovaries become temporarily enlarged. Up to 2.0 % of women will develop Ovarian Hyperstimulation Syndrome (OHSS) [see full discussion of OHSS in the Risks to Women section that follows]. Other risks and side effects of gonadotropins include, but are not limited to, fatigue, headaches, weight gain, mood swings, nausea, and clots in blood vessels.

Even with pre-treatment attempts to assess response, and even more so with abnormal pre-treatment evaluations of ovarian reserve, the stimulation may result in very few follicles developing. The end result may be few or no eggs obtained at egg retrieval or even cancellation of the treatment cycle prior to egg retrieval.

Concerns have been raised that the risk of ovarian cancer may increase with the use of fertility drugs, but recent studies have not confirmed this. A major risk factor for ovarian cancer is infertility per se, and early reports may have falsely attributed the risk resulting from infertility to the use of medications to overcome it (see 2.b.2 for further discussion).

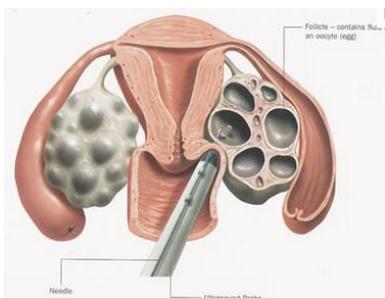
- **GnRH-agonists (leuprolide acetate) (Lupron®)**: This medication is taken by injection. There are two forms of the medication: A short acting medication requiring daily injections and a long-acting preparation lasting for 1-3 months. The primary role of this medication is to prevent a premature LH 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.
- **GnRH-antagonists (ganirelix acetate or cetrotide acetate) (Ganirelix®, Cetrotide®)**: These are another class of medications used to prevent premature ovulation. They tend to be used for short periods of time in the late stages of ovarian stimulation. The 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®)**: hCG is a natural hormone used in IVF to induce the eggs to become mature and fertilizable. The timing of this medication is critical to retrieve mature eggs. Potential side effects include, but are not limited to: breast tenderness, bloating, and pelvic discomfort.
- **Progesterone, and in some cases, estradiol**: Progesterone and estradiol are hormones normally produced by the ovaries after ovulation. After egg retrieval in some women, the ovaries will not produce adequate amounts

of these hormones for long enough to fully support a pregnancy. Accordingly, supplemental progesterone, and in some cases estradiol, are given to ensure adequate hormonal support of the uterine lining. Progesterone is usually given by injection or by the vaginal route (Endometrin®, Crinone®, Prochieve®, Prometrium®, or pharmacist-compounded suppositories) after egg retrieval. 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, aspirin, testosterone, DHEA, CoQ10, intravenous gamma globulin infusion and others may also be included in the treatment protocol.

Transvaginal Oocyte (Egg) Retrieval

- Eggs are removed from the ovary with a needle under ultrasound guidance.
- Anesthesia is provided to make this comfortable.
- Complications are rare.



Oocyte retrieval is the removal of eggs from the ovary. A transvaginal ultrasound probe is used to visualize the ovaries and the egg-containing follicles within the ovaries. A long needle, which can be seen on ultrasound, can be guided into each follicle and the contents aspirated. The aspirated material includes follicular fluid, oocytes (eggs) and granulosa (egg-supporting) cells. Rarely, the ovaries are not accessible by the transvaginal route and laparoscopy or trans-abdominal retrieval is necessary. These procedures and risks will be discussed with you by your doctor if applicable. Anesthesia is generally used to reduce, if not eliminate, discomfort. Risks of egg retrieval include:

Infection: Bacteria normally present in the vagina may be inadvertently transferred into the abdominal cavity by the needle. These bacteria may cause an infection of the uterus, fallopian tubes, ovaries or other intra-abdominal organs. The estimated incidence of infection after egg retrieval is less than 0.1%. Treatment of infections could require the use of oral or intravenous antibiotics. Severe infections occasionally require surgery to remove infected tissue. Infections can have a negative impact on future fertility. Prophylactic antibiotics are sometimes used before the egg retrieval procedure to reduce the risk of pelvic or abdominal infection in patients at higher risk of this complication. Despite the use of antibiotics, there is no way to eliminate this risk completely.

Bleeding: The needle passes through the vaginal wall and into the ovary to obtain the eggs. Both of these structures contain blood vessels. In addition, there are other blood vessels nearby. Small amounts of blood loss are common during egg retrievals. The incidence of major bleeding problems has been estimated to be less than 0.1%. Major bleeding may require surgical repair and possibly loss of the ovary. The need for blood transfusion is rare. (Although very rare, review of the world experience with IVF indicates that unrecognized bleeding has led to death.)

Trauma: Despite the use of ultrasound guidance, it is possible to damage other intra-abdominal organs during the egg retrieval. Previous reports in the medical literature have noted damage to the bowel, appendix, bladder, ureters, and ovary. Damage to internal organs may result in the need for additional treatment such as surgery for repair or removal of the damaged organ. However, the risk of such trauma is very low.

Anesthesia: The use of anesthesia during the egg retrieval can produce unintended complications such as an allergic reaction, low blood pressure, nausea or vomiting and in rare cases, death.

Failure: It is possible that the aspiration will fail to obtain any eggs or the eggs may be abnormal or of poor quality and otherwise fail to produce a viable pregnancy.

In vitro fertilization and embryo culture

- **Sperm and eggs are placed together in specialized conditions (culture media, controlled temperature, humidity and light) to achieve fertilization.**
- **Culture medium is designed to permit normal fertilization and early embryo development, but the content of the medium is not standardized.**
- **Embryo development in the lab helps distinguish embryos with more potential from those with less or none.**

After eggs are retrieved, they are transferred to the embryology laboratory where they are kept in conditions that support their needs and growth. The eggs are placed in small dishes or tubes containing "culture medium," which is special fluid developed to support development of the eggs and embryos made to resemble that found in the fallopian tube or uterus. The dishes containing the eggs are then placed into incubators, which control the temperature and atmospheric gasses the eggs and embryos experience.

A few hours after eggs are retrieved, sperm are placed in the culture medium with the eggs, or individual sperm are injected into each mature egg in a technique called Intracytoplasmic Sperm Injection (ICSI) (see below). The eggs are then returned to the incubator, where they remain to develop. Periodically over the next few days, the dishes are inspected so the development of the embryos can be assessed.

The following day after eggs have been inseminated or injected with a single sperm (ICSI), they are examined for signs that the process of fertilization is underway. At this stage, normal development is evident by the still single cell having 2 nuclei; this stage is called a zygote or a 2PN embryo. Two days after insemination or ICSI, normal embryos have divided into about 4 cells. Three days after insemination or ICSI, normally developing embryos contain about 8 cells. Five days after insemination or ICSI, normally developing embryos have developed to the blastocyst stage, which is typified by an embryo that now has 80 or more cells, an inner fluid-filled cavity, and a small cluster of cells called the inner cell mass.

It is important to note that since many eggs and embryos are abnormal, it is expected that not all eggs will fertilize and not all embryos will divide at a normal rate. The chance that a developing embryo will produce a pregnancy is related to many factors including whether its development in the lab is normal, but this correlation is not perfect. This means that not all embryos developing at the normal rate are in fact also genetically normal, and not all poorly developing embryos are genetically abnormal. Nonetheless, their visual appearance is the most common and useful guide in the selection of the best embryo(s) for transfer.

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

- Fertilization of the egg(s) may fail to occur.
- An egg may be fertilized abnormally resulting in an abnormal number of chromosomes in the embryo; these abnormal embryos will not be transferred.
- The fertilized eggs may degenerate before dividing into embryos, or adequate embryonic development may fail to occur.
- Bacterial contamination or a laboratory accident may result in loss or damage to some or all of the eggs or embryos.
- Laboratory equipment may fail, and/or extended power losses can occur which could lead to the destruction of eggs, sperm and embryos.
- Other unforeseen circumstances may prevent any step of the procedure to be performed or prevent the establishment of a pregnancy.
- Hurricanes, floods, or other "acts of God" (including bombings or other terrorist acts) could destroy the laboratory or its contents, including any sperm, eggs, or embryos being stored there.

Quality control in the lab is extremely important. Sometimes immature or unfertilized eggs, sperm or abnormal embryos (abnormally fertilized eggs or embryos whose lack of development indicates they are not of sufficient quality to be transferred) that would normally be discarded can be used for quality control. This material may be used for quality control purposes before being discarded in accordance with normal laboratory procedures and applicable laws. None of this material will be utilized to establish a pregnancy or a cell line.

I / We hereby CONSENT to allow the clinic to utilize my/our immature or unfertilized eggs, left-over sperm or abnormal embryos for quality control and training purposes before they are discarded.

Patient:

Date:

Spouse/Partner:

Date:

I / We hereby DO NOT CONSENT to allow the clinic to utilize my/our immature or unfertilized eggs, left-over sperm or abnormal embryos for quality control and training purposes. This material will be discarded in accordance with normal laboratory procedures and applicable laws.

Patient:

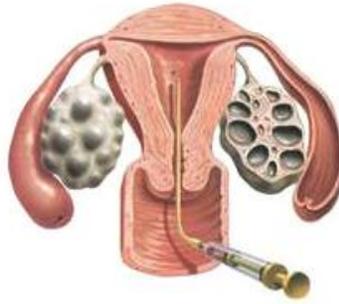
Date:

Spouse/Partner:

Date:

Embryo transfer

- After a few days of development, the best appearing embryos are selected for transfer.
- The number chosen influences the pregnancy rate and the multiple pregnancy rate.
- A woman's age and the appearance of the developing embryo have the greatest influences on pregnancy outcome.
- Embryos are placed in the uterine cavity with a thin tube.
- Excess embryos of sufficient quality that are not transferred can be frozen.



After a few days of development, one or more embryos are selected for transfer to the uterine cavity. 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 2013 recommend limits on the number of embryos to transfer (see Tables below). These limits should not 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.

Recommended limits on the number of embryos to transfer

	Age < 35	Age 35-37	Age 38-40	Age >40
Embryos				
--favorable	1 or 2	2	3	5
--not favorable	2	3	4	5
Blastocysts				
--favorable	1	2	3	3
--not favorable	2	2	3	3

In many cases, a final determination of embryo quality and quantity, and therefore, recommended number of embryos to be transferred cannot be done until day of embryo transfer. A final recommendation can therefore only be made on this day. Patients and their partners will therefore be once again consented on that day. If the female's partner cannot be available for the consent process on that day, he has to sign the following statement at this point:

I, _____ hereby authorize my female partner on day of the embryo transfer, in my absence, to make a final decision about the number of embryos to be transferred.

X _____ Date _____
Male Partner Signature

X _____ Date _____
Male Partner Printed Name

In some cases, there will be additional embryos remaining in the lab after the transfer is completed. Depending on their developmental normalcy, it may be possible to freeze them for later use.

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 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.

Additional Elements

Intracytoplasmic Sperm Injection (ICSI)

- **ICSI is used to increase the chance of fertilization when fertilization rates are anticipated to be lower than normal.**
- **Overall success rates with ICSI are slightly lower than for conventional insemination.**
- **An increased risk of genetic defects in offspring is reported.**
- **ICSI will not improve oocyte defects.**

The use of ICSI provides an effective treatment for male factor infertility. The negative effects of abnormal semen characteristics and sperm quality on fertilization can be overcome with ICSI if viable sperm are available because the technique bypasses the shell around the egg (zona pellucida) and the egg membrane (oolemma) to deliver the sperm directly into the egg. ICSI involves the direct injection of a single sperm into the interior of an egg using an extremely thin glass needle. ICSI allows couples with male factor infertility to achieve fertilization and live birth rates similar to those achieved with in vitro fertilization (IVF) using conventional methods of fertilization in men with normal sperm counts. ICSI can be performed even in men with no sperm in the ejaculate if sperm can be successfully collected from the epididymis or the testis.

ICSI is associated with a slightly higher risk of birth defects. Whether this association is due to the ICSI procedure itself or to inherent sperm defects has not been determined. The impact of ICSI on the intellectual and motor development of children has also been controversial, but recent studies have not detected any differences in the development of children born after ICSI, conventional IVF, or natural conception.

Certain genetic abnormalities have been shown to increase in IVF offspring. The prevalence of sex chromosome (X and Y) abnormalities in children conceived via ICSI is higher than observed in the general IVF population, but the difference between the two groups is small (0.8% to 1.0% in ICSI offspring vs. 0.2% in the general IVF population). Translocations (a re-arrangement of chromosomes that can cause miscarriage) may be more common in ICSI offspring (0.36%) than in the general population (0.07%). Although these differences might result from the ICSI procedure itself, men with abnormal semen analyses are more likely themselves to have chromosome abnormalities and may produce sperm with abnormal chromosomes. These abnormalities could be passed to their offspring.

Some men with extremely low or absent sperm counts have small deletions on their Y chromosome. When viable sperm can be obtained to fertilize eggs with ICSI, sperm containing a Y chromosomal microdeletion may result in male offspring who also carry the microdeletion and may be infertile. A Y chromosome microdeletion can often, but not always, be detected by a blood test.

Men who are infertile because of congenital bilateral absence of the vas deferens (CBAVD) are affected with a mild form of cystic fibrosis (CF). When sperm aspiration and ICSI results in conception, the CF gene will be passed on to the offspring. Men with CBAVD and their partners should be tested for CF gene mutations prior to treatment. However, some CF mutations may not be detected by current testing, so that some parents who test negative for CF mutations could still have affected children.

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.

Some programs have incorporated artificial or “assisted hatching” into their treatment protocols 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.

Cryopreservation

- **Freezing of eggs and embryos can provide additional chances for pregnancy.**
- **Frozen eggs and embryos do not always survive the process of freezing and thawing.**
- **Ethical and legal dilemmas can arise when couples separate or divorce, especially for embryos; disposition agreements are essential.**
- **It is the responsibility of each couple with frozen eggs and / or embryos to remain in contact with the clinic on an annual basis.**

Freezing (or “cryopreservation”) of eggs or embryos is a common procedure. Since multiple eggs (oocytes) are often produced during ovarian stimulation, on occasion there are more embryos available than are considered appropriate for transfer to the uterus. Such embryos can be frozen for future use. Alternatively, some eggs can be frozen before being exposed to sperm. Both strategies save the expense and inconvenience of stimulation to obtain additional eggs in the future. Furthermore, the availability of cryopreservation permits patients to transfer fewer embryos during a fresh cycle, reducing the risk of high-order multiple gestations (triplets or greater). Other possible reasons for cryopreservation of embryos include freezing all embryos in the initial cycle to prevent severe ovarian hyperstimulation syndrome (OHSS), or if a couple were concerned that their future fertility potential might be reduced due to necessary medical treatment (e.g., cancer therapy or surgery). The pregnancy success rates for cryopreserved embryos transferred into the human uterus can vary from practice to practice. Overall pregnancy rates at the national level with frozen embryos are lower than with fresh embryos. This, at least in part, results from the routine selection of the best-looking embryos for fresh transfer, reserving the “second-best” for freezing. There is some evidence that pregnancy rates are similar when there is no such selection.

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 decrease the risks of hyperstimulation (OHSS- see below) by freezing all embryos, when this risk is high

Risks of cryopreservation: There are several techniques for embryo cryopreservation, and research is ongoing. Traditional methods include “slow,” graduated freezing in a computerized setting, and “rapid” freezing methods, called “vitrification.” Current techniques deliver a high percentage of viable eggs and embryos thawed after cryopreservation, but there can be no certainty that eggs and embryos will thaw normally, nor be viable enough to divide and eventually implant in the uterus. Cryopreservation techniques could theoretically be injurious to the embryo. Extensive animal data (through several generations), and limited human 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. However, until very large numbers of children have been born following freezing and thawing of embryos, it is not possible to be certain that the rate of abnormalities is no different from the normal rate.

If you choose to freeze eggs or embryos, you MUST complete in the office or notarize the Disposition of Eggs or Disposition of Embryos statement before freezing. This statement outlines the choices you have with regard to the disposition of embryos in a variety of situations that may arise. You are free to submit a statement at a later time indicating different choices, provided you both agree in writing. It is also incumbent upon you to remain in touch with the clinic regarding your residence, and to pay for storage charges as they come due.

Risks to the Woman

Ovarian Hyperstimulation Syndrome

The intent of giving gonadotropins is to mature multiple follicles, but some women have an excessive response to the medications and are at risk for ovarian hyperstimulation syndrome (OHSS). This is the most serious side effect of ovarian stimulation. Its symptoms can include increased ovarian size, nausea and vomiting, accumulation of fluid in the abdomen, breathing difficulties, an increased concentration of red blood cells, kidney and liver problems, and in the most severe cases, blood clots, kidney failure, or death. The severe cases affect only a very small percentage of women who undergo in vitro fertilization—0.2 percent or less of all treatment cycles—and the very severe are an even smaller percentage. Only about 1.4 in 100,000 cycles has led to kidney failure, for example. OHSS occurs at two stages: early, 1 to 5 days after egg retrieval (as a result of the hCG trigger); and late, 10 to 15 days after retrieval (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 no embryo transfer is performed to reduce the possibility of this occurring.

Cancer

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. A final answer may require decades of follow-up to resolve. Note that an increased chance for “borderline” ovarian tumors has been observed with IVF, even when compared to the subfertile population (see reference section for citation). More research is required to examine what the long-term impact fertility drugs may have on breast and ovarian cancer prevalence rates. For uterine cancer, the numbers are too small to achieve statistical significance, but it is at least possible that use of fertility drugs may indeed cause some increased risk of uterine cancer.

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

	Absolute Risk (%) in IVF-conceived Pregnancies	Relative Risk (vs. non IVF-conceived Pregnancies in a control population)	Relative Risk of Non-IVF Infertile Patients (vs. control population)
Pre-eclampsia	10.3%	1.6 (1.2--2.0)	1.29 (1.02-1.61)
Placenta previa	2.4%	2.9 (1.5--5.4)	
Placental abruption	2.2%	2.4 (1.1--5.2)	
Gestational diabetes	6.8%	2.0 (1.4--3.0)	1.25 (0.96-1.63)
Cesarean delivery *	26.7%	2.1 (1.7--2.6)	1.56 (1.37-1.77)

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.

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.

Potential Risks in Singleton IVF Pregnancies

	Absolute Risk (%) in IVF Pregnancies	Relative Risk (vs. non- IVF Pregnancies)	Relative Risk for infertile women without ART
Preterm birth	11.5%	2.0 (1.7--2.2)	1.32 (1.05-1.67)
Low birth weight (< 2500 g)	9.5%	1.8 (1.4--2.2)	1.44 (1.11-1.85)
Very low birth weight (< 1500 g)	2.5%	2.7 (2.3--3.1)	
Small for gestational age	14.6%	1.6 (1.3--2.0)	0.99
NICU (intensive care) admission	17.8%	1.6 (1.3--2.0)	
Stillbirth	1.2%	2.6 (1.8--3.6)	
Neonatal mortality	0.6%	2.0 (1.2--3.4)	2.19 (1.10-4.36)
Cerebral palsy	0.4%	2.8 (1.3--5.8)	
Genetic risks			
-imprinting disorder	0.03%	17.8 (1.8--432.9)	
-major birth defect	4.3%	1.5 (1.3--1.8)	
-chromosomal abnormalities after ICSI			
-of a sex chromosome	0.6%	3.0	
-of another chromosome	0.4%	5.7	

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 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. The numbers in parentheses (called the "Confidence Interval") indicate the range in which the actual relative risk lies.

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 ethic 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).

Alternatives to IVF

There are alternatives to IVF treatment including gamete Intrafallopian transfer (GIFT), zygote intrafallopian transfer (ZIFT) or tubal embryo transfer (TET) where eggs and sperm, fertilized eggs or developing embryos, respectively, are placed into the fallopian tube(s). Using donor sperm, donor eggs, adoption, or not pursuing treatment are also options. Gametes (sperm and/or eggs), instead of embryos may be frozen for future attempts at pregnancy in an effort to avoid potential future legal or ethical issues relating to disposition of any cryopreserved embryos. Sperm freezing, but not egg freezing, has been an established procedure for many decades.

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.

Additional Information

General IVF overviews available on the internet

www.reproductivefacts.org

www.sart.org/

www.cdc.gov/art/

www.resolve.org/site/PageServer

Number of Embryos to Transfer

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

Culturing Embryos to the Blastocyst Stage

Blastocyst culture and transfer in clinical-assisted reproduction. The Practice Committee of the American Society for Reproductive Medicine and the Practice Committee of the Society for Assisted Reproductive Technology. *Fertil Steril* 2006; 86 (suppl 4): S89-S92.

Intracytoplasmic sperm injection

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

Embryo hatching

The role of assisted hatching in in vitro fertilization: a review of the literature. A Committee opinion. The Practice Committee of the American Society for Reproductive Medicine and the Practice Committee of the Society for Assisted Reproductive Technology. *Fertil Steril* 2006; 86 (suppl. 4): S124-S126.

Ovarian Hyperstimulation

Ovarian hyperstimulation syndrome. The Practice Committees of the American Society for Reproductive Medicine. *Fertil Steril* 2006; 86 (suppl 4): S178-S183.

Risks of pregnancy

Infertility, assisted reproductive technology, and adverse pregnancy outcomes. Executive Summary of a National Institute of Child Health and Human Development Workshop. Reddy UM, Wapner RJ, Rebar RW, Tasca RJ. *Obstet Gynecol* 2007; 109(4):967-77. Risk of borderline and invasive tumours after ovarian stimulation for *in vitro fertilization* in a large Dutch cohort. FE van Leeuwen, H Klip, et al. *Human Reproduction*, 2011;26(12):3456-65.

Risks to offspring

Infertility, assisted reproductive technology, and adverse pregnancy outcomes. Executive Summary of a National Institute of Child Health and Human Development Workshop. Reddy UM, Wapner RJ, Rebar RW, Tasca RJ. *Obstet Gynecol* 2007; 109(4):967-77. Multiple pregnancy associated with infertility therapy. The Practice Committees of the American Society for Reproductive Medicine *Fertil Steril* 2006; 86 (suppl 4): S106-S110. Imprinting diseases and IVF: A Danish National IVF cohort study. Lidegaard O, Pinborg A and Anderson AN. *Human Reproduction* 2005; 20(4):950-954. Bergh C, Wennerholm U-B. Obstetric outcome and long-term follow up of children conceived through assisted reproduction. *Best Practice & Research Clinical Obstetrics and Gynaecology* (2012), doi:10.1016/j.bpobgyn.2012.05.001. Davies MJ, Moore VM, Willson KJ, Van Essen P, Priest K, Scott H, Haan EA, Chan A. Reproductive Technologies and the risk of birth defects. *N Engl J Med* 2012;366:1803-13. Doi:10.1056/NEJMoa1008095). Reproductive technologies and the risk of birth defects. MJ Davies, VM Moore, et al. *New England Journal of Medicine* 2012; 366(19):1803-13.

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

X

Patient Signature

Date

Patient Name

Date of Birth

Witness

Date

Notary Public

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

Notary Signature

Date

X

Spouse / Partner Signature

Date

Spouse / Partner Name

Date of Birth

Witness

Date

Notary Public

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

Notary Signature

Date

Patient initial

Partner initial

IVF Treatment Plan

Patient name: _____ Date: _____

Spouse / partner name: _____ for IVF when? _____

Provider of Sperm.

We (I) plan to use sperm from:

- Spouse / partner
- Donor (specify name or number): _____
- Other (specify arrangement): _____

Initials: _____ / _____

Carrier of Embryos.

We (I) plan to transfer the embryos into:

- Me, the intended parent
- A Gestational Carrier
----if known, her name: _____

Initials: _____ / _____

Method of Insemination.

We (I) acknowledge that we (I) have discussed the possibility of the need for ICSI with our (my) physician and understand, agree and consent that:

- ICSI **will be** used.
- ICSI **will not** be used.
- ICSI **will not** be used, unless the semen at time of egg retrieval is sub-optimal based on the best medical judgment of the CHR staff, or the initial fertilization is poor. In these cases ICSI may be used. We (I) understand that we (I) will be notified if ICSI is performed.

Initials: _____ / _____

Limit on Number Inseminated?

Regarding the number of eggs to expose to sperm, we (I) choose:

- Inseminate ALL Mature Eggs
- Inseminate SOME Mature Eggs
Number or fraction of eggs to be exposed to sperm: _____

Initials: _____ / _____

Assisted Zona/Embryo Hatching:

We (I) acknowledge that we (I) have discussed the possibility of the need for AZH with our (my) physician and understand, agree and consent that:

- AZH **will be** used.
- AZH **will not** be used.
- AZH **will not** be used, unless based on the best medical judgment of the CHR staff, in that case AZH may be used. We (I) understand that we (I) will be notified if AZH is performed.

Initials: _____ / _____

Plan for Eggs NOT Inseminated (if applicable).

Regarding the eggs not exposed to sperm for fertilization we (I) choose:

- Freeze for my later use (requires Disposition Declaration)
- Donate to:
 - Research
 - Another person or couple
- Discard. This disposal will follow ASRM Ethical Guidelines. These extra eggs will no longer be available for attempting a pregnancy.

Initials: _____ / _____

Products of IVF Cycles Destined to be Discarded and Their Use in Research at CHR

Members of CHR's have advised us that in the normal course of an IVF procedure/cycle oocytes (eggs) and embryos are routinely discarded by embryologists if, based on their best professional judgment, said eggs/embryos are abnormal and/or not judged viable. Lab staff will also dispose of excessive blood (samples) and semen, unless specific instructions were received from patients prior to the procedure in writing to preserve such excessive sperm, or take other action with it.

By signing this consent form you acknowledge that blood (or blood products), eggs, sperm or embryos, granulosa cells, cumulus cells and follicular fluid so destined for disposition, may be further examined in biochemical and/or genetic tests and/or retained by CHR for limited time periods for educational or other research purposes but, ultimately, will be disposed in accordance with practice.

If you disagree with such potential use for educational or research purposes, please initial between both arrows. → ←

Plan for Embryos NOT Transferred.

Regarding the disposition of embryos not transferred, we (I) elect the following option:

- Freeze Excess Embryos** (requires Disposition Declaration)

- Donate Excess Embryos to:**
 - Research
 - Another person or couple

- Discard Excess Embryos.** This disposal will follow ASRM Ethical Guidelines. These extra embryos will no longer be available for attempting a pregnancy.

Initials: _____ / _____

Plan for Preimplantation Genetic Testing / Screening.

We (I) choose:

- No genetic testing / screening of embryos**
- Genetic testing of all embryos no matter how few are available**
- Genetic testing of all embryos if enough are available to test** (in consultation with embryology lab staff).

Initials: _____ / _____

Patient signature: _____

Partner / spouse signature: _____

CHR Staff signature: _____

Date: _____

Revised 2/5/2014



THE CENTER FOR HUMAN REPRODUCTION (CHR)

21 East 69th Street, New York, NY 10021 T: 212-994-4400; F: 212-994-4499

Disposition of Embryos Declaration of Intent

Adopted on: 2/6/2014

Because of the possibility of you and/or your partner's separation, divorce, death or incapacitation after embryos have been produced, it is important to decide on the disposition of any embryos (fresh or cryopreserved) that remain in the laboratory in these situations. Since this is a rapidly evolving field, both medically and legally, the clinic cannot guarantee what the available or acceptable avenues for disposition will be at any future date.

Currently, the alternatives are:

1. Discarding the cryopreserved embryo(s)
2. Donating the cryopreserved embryo(s) for approved research studies
3. Donating the cryopreserved embryos to another couple in order to attempt pregnancy. (In this case, you may be required to undergo additional infectious disease testing and screening due to federal or state requirements.)
4. Use by one partner with the contemporaneous permission of the other for that use

This declaration provides several choices for disposition of embryos in these circumstances (death of the patient or the patient's spouse or partner, separation or divorce of the patient and her spouse/partner, successful completion of IVF treatment, decision to discontinue IVF treatment, and by failure to pay fees for frozen storage).

I/We agree that in the absence of a more recent written and witnessed consent form, the Clinic is authorized to act on our choices indicated below, so far as it is practical.

I/We also agree that in the event that either our chosen dispositional choices are not available or I/we fail to preserve any choices made herein, whether through nonpayment of storage fees or otherwise, the clinic is authorized to discard and destroy our embryos.

Note:

- Embryos cannot be used to produce pregnancy against the wishes of the partner. For example, in the event of a separation or divorce, embryos cannot be used to create a pregnancy without the express, written consent of both parties, even if donor gametes were used to create the embryos.
- Disposition of embryos that are created using donated sperm or eggs may be subject to prior enforceable agreements that you have entered into with a sperm, egg or embryo donor. The Clinic may need to review these agreements before accepting the sperm, eggs, or embryos and/or before using them for procreation or research purposes.
- Embryo donation for research purposes may be restricted by applicable state or federal laws that govern your jurisdiction. In the case of embryos created using donated sperm or eggs, donation to research may be restricted or may require the contemporaneous written consent of the sperm or egg donor. Patients are advised to check applicable laws or regulations governing research donation of embryos formed via sperm or egg donation.

Patient initial

Partner initial

- Embryo donation to achieve a pregnancy is regulated by the FDA (U.S. Food and Drug Administration), as well as state laws, as donated tissue. Certain screening and testing of the persons providing the sperm and eggs are required before donation can occur.
- You are free to revise the choices you indicate here at any time by completing another form in the office or having it notarized.
- Your wills should also include your wishes on disposition of the embryos and be consistent with this consent form. Any discrepancies will need to be resolved by court decree.
- Please check the appropriate box in each section to delineate your wishes and initial the bottom of each page.

Death of Patient

In the event the patient dies prior to use of all the embryos, I/we agree that the embryos should be disposed of in the following manner (check only one box):

- Award to patient's spouse or partner, which gives complete control for any purpose, including implantation, donation for research, or destruction. This may entail maintaining the embryos in storage, and the fees and other payments due the clinic for these cryopreservation services.
- Donate to another couple or individual for reproductive purposes. This may entail maintaining the embryos in storage, and the fees and other payments due the clinic for these cryopreservation services. If you wish, you may designate a couple or individual to receive the embryos. In the event the designated couple or individual is unable or unwilling to accept the embryos, the clinic will control the donation.

Please donate to: Name _____
 Address _____
 Telephone _____
 Email _____

Special note for embryos created with gamete donors: If your embryos were formed using gametes (eggs or sperm) from a known third-party donor, your instruction to donate these embryos to another couple or individual must be consistent with and in accordance with any and all prior agreements made with the gamete donor(s). If anonymous donor gametes were used, written authorization from the gamete donor must have been obtained to use these gametes for anything other than reproduction or destruction of the embryos.

- Award for research purposes, including but not limited to embryonic stem cell research, which may result in the destruction of the embryos, but will not result in the birth of a child.
- Destroy the embryos.
- Other disposition (please specify): _____

Death of Spouse or Partner

In the event the patient's spouse or partner dies prior to use of all the embryos, I/we agree that the embryos should be disposed of in the following manner (check one box only):

- Award to patient, which gives complete control for any purpose, including implantation, donation for research, or destruction. This may entail maintaining the embryos in storage, and the fees and other payments due the clinic for these cryopreservation services.
- Donate to another couple or individual for reproductive purposes. This may entail maintaining the embryos in storage, and the fees and other payments due the clinic for these cryopreservation services. If you wish, you may designate a couple or individual to receive the embryos. In the event the designated couple or individual is unable or unwilling to accept the embryos, the clinic will control the donation.

Please donate to: Name _____
 Address _____
 Telephone _____
 Email _____

Special note for embryos created with gamete donors: If your embryos were formed using gametes (eggs or sperm) from a known third-party donor, your instruction to donate these embryos to another couple or individual must be consistent with and in accordance with any and all prior agreements made with the gamete donor(s). If anonymous donor gametes were used, written authorization from the gamete donor must be obtained to use these gametes for anything other than reproduction or destruction of the embryos.

- Award for research purposes, including but not limited to embryonic stem cell research, which may result in the destruction of the embryos, but will not result in the birth of a child.
- Destroy the embryos.
- Other disposition (please specify): _____

Simultaneous Death of Patient and Spouse or Partner

In the event the patient and her spouse or partner die at the same time, prior to use of all the embryos, I/we agree that the embryos should be disposed of in the following manner (check one box only):

- Donate to another couple or individual for reproductive purposes. This may entail maintaining the embryos in storage, and the fees and other payments due the clinic for these cryopreservation services. If you wish, you may designate a couple or individual to receive the embryos. In the event the designated couple or individual is unable or unwilling to accept the embryos, the clinic will control the donation.

Please donate to: Name _____
 Address _____
 Telephone _____
 Email _____

Special note for embryos created with gamete donors: If your embryos were formed using gametes (eggs or sperm) from a known third-party donor, your instruction to donate these embryos to another couple or individual must be consistent with and in accordance with any and all prior agreements made with the gamete donor(s). If anonymous donor gametes were used, written authorization from the gamete donor must be obtained to use these gametes for anything other than reproduction or destruction of the embryos.

- Award for research purposes, including but not limited to embryonic stem cell research, which may result in the destruction of the embryos, but will not result in the birth of a child.
- Destroy the embryos.
- Other disposition (please specify): _____

Divorce or Dissolution of Relationship

In the event the patient and her spouse are divorced or the patient and her partner dissolve their relationship, I/we agree that the embryos should be disposed of in the following manner (check one box only):

- A court decree and/or settlement agreement will be presented to the Clinic directing use to achieve a pregnancy in one of us or donation to another couple for that purpose.
- Award for research purposes, including but not limited to embryonic stem cell research, which may result in the destruction of the embryos, but will not result in the birth of a child.
- Destroy the embryos.

Discontinuation of IVF Treatment

In the event the patient and her spouse or partner mutually agree to discontinue IVF treatment as a couple, I/we agree that any embryos should be disposed of in the following manner (check one box only):

- Award to patient, which gives complete control for any purpose, including implantation, donation for research, or destruction. This may entail maintaining the embryos in storage, and the fees and other payments due the clinic for these cryopreservation services.
- Award to spouse or partner, which gives complete control for any purpose, including implantation, donation for research, or destruction. This may entail maintaining the embryos in storage, and the fees and other payments due the clinic for these cryopreservation services.
- Donate to another couple or individual for reproductive purposes. If you wish, you may designate a couple or individual to receive the embryos. In the event the designated couple or individual is unable or unwilling to accept the frozen embryos, the clinic will control the donation.

Please donate to: Name _____
 Address _____
 Telephone _____
 Email _____

Special note for embryos created with gamete donors: If your embryos were formed using gametes (eggs or sperm) from a known third-party donor, your instruction to donate these embryos to another couple or individual must be consistent with and in accordance with any and all prior agreements made with the gamete donor(s). If anonymous donor gametes were used, written authorization from the gamete donor must be obtained to use these gametes for anything other than reproduction or destruction of the embryos.

- Award for research purposes, including but not limited to embryonic stem cell research, which may result in the destruction of the embryos, but will not result in the birth of a child.
- Destroy the embryos.
- Other disposition (please specify): _____

Nonpayment of Cryopreservation Storage Fees

Maintaining embryo(s) in a frozen state is labor intensive and expensive. There are fees associated with freezing and maintaining cryopreserved embryo(s). Patients/couples who have frozen embryo(s) must remain in contact with the clinic on an annual basis in order to inform the clinic of their wishes as well as to pay fees associated with the storage of their embryo(s). In situations where there is no contact with the clinic for a period of one (1) year or fees associated with embryo storage have not been paid for a period of one (1) year and the clinic is unable to contact the patient after reasonable efforts have been made (via registered mail at last known address), the embryo(s) may be destroyed by the clinic in accordance with normal laboratory procedures and applicable law.

If I/we fail to pay the overdue storage fees within 30 days from the date of said mailing, such failure to pay constitutes my/our express authorization to the clinic to follow the disposition instructions we have elected below without further communications to or from us (check one box only):

- Award for research purposes, including but not limited to embryonic stem cell research, which may result in the destruction of the frozen embryos, but will not result in the birth of a child.
- Destroy the frozen embryos.

Time-Limited Storage of Embryos

The Clinic will only maintain cryopreserved embryos for a period of Three (3) years. After that time, I/we elect (check one box only):

- Award for research purposes, including but not limited to embryonic stem cell research, which may result in the destruction of the frozen embryos, but will not result in the birth of a child.
- Destroy the frozen embryos.
- Require renewal of consent.

Donation of Frozen Embryos for Research Purposes

If you selected the option “award for research purposes” under any of the preceding circumstances, as a donor of human embryos to research, including but not limited to stem cell research, you should be aware of the following:

- Donating embryo(s) for research may not be possible or may be restricted by law. While efforts will be made to abide by your wishes, no guarantees can be given that embryo(s) will be used for research or donated to another couple. In these instances, if after three (3) years no recipient or research project can be found, or your embryos are not eligible, your embryo(s) will be destroyed and discarded by the lab in accordance with laboratory procedures and applicable laws.
- The embryos may be used to derive human pluripotent stem cells for research and the cells may be used, at some future time, for human transplantation research.
- All identifiers associated with the embryos will be removed prior to the derivation of human pluripotent stem cells.
- Donors to research will not receive any information about subsequent testing on the embryo or the derived human pluripotent cells.
- Derived cells or cell lines, with all identifiers removed, may be kept for many years.
- It is possible the donated material may have commercial potential, but the donor will receive no financial or other benefit from any future commercial development.
- Human pluripotent stem cell research is not intended to provide direct medical benefit to the embryo donor.
- Donated embryos will not be transferred to a woman’s uterus, nor will the embryos survive the human pluripotent stem cell derivation process. Embryos will be handled respectfully, as is appropriate for all human tissue used in research. If the donated embryos were formed with gametes (eggs or sperm) from someone other than the patient and her spouse or partner (those who sign this document), the gamete donor(s) may be required to provide a signed, written consent for use of the resulting embryos for research purposes.

Legal Considerations and Legal Counsel

The law regarding embryo cryopreservation, subsequent thaw and use, and parent-child status of any resulting child(ren) is, or may be, unsettled in the state in which either the patient, spouse, partner, or any donor currently or in the future lives, or the state in which the ART Program is located. We acknowledge that the ART Program has not given us legal advice, that we are not relying on the ART Program to give us any legal advice, and that we have been informed that we may wish to consult a lawyer who is experienced in the areas of reproductive law and embryo cryopreservation and disposition if we have any questions or concerns about the present or future status of our embryos, our individual or joint access to them, our individual or joint parental status as to any resulting child, or about any other aspect of this consent and agreement.

Our signatures below certify the disposition selections we have made above. We understand that we can change our selections in the future, but need mutual and written agreement as outlined above. We also understand that in the event that none of our elected choices is available, the clinic is authorized, without further notice from us, to destroy and discard our frozen embryos.

<u>X</u> Patient Signature	_____	_____	Date
_____	Patient Name	_____	Date of Birth
_____	CHR Witness	_____	Date
Notary Public Sworn and subscribed before me on this ____ day of _____, _____.			
_____	Notary Signature	_____	Date
<u>X</u> Spouse / Partner Signature (if applicable)	_____	_____	Date
_____	Spouse / Partner Name	_____	Date of Birth
_____	CHR Witness	_____	Date
Notary Public Sworn and subscribed before me on this ____ day of _____, _____.			
_____	Notary Signature	_____	Date

Informed Consent for the Administration of Fertility Enhancing Medications

I understand that the potential risks of the use of fertility enhancing medications include, amongst Others, the following:

1. The development of the so-called *Hyper stimulation Syndrome*, which, in general, manifests itself as enlarged, tender ovaries and often is accompanied by bloating, abdominal pain, can be associated with vomiting and may, on rare occasions, become a "life threatening condition, requiring hospitalization and even intensive care.
2. The risk of a multiple pregnancy, which ranges from approximately 5 to 25%, depending on the medication used and the patient's underlying diagnosis.
3. The potentially increased risks of developing ovarian, breast and other cancers. Most studies have refutes such a risk; however, the issue should be considered as still under investigation.
4. Allergic reactions to the medications.
5. Like most medications, fertility enhancing medications may have additional risk, not listed here and we, therefore, recommend a detailed reading of the package inserts, accompanying all medications prescribed at CHR.

I also understand that these drugs will require self-administration and that most of them are administered by injection. My responsibility will be to administer these drugs precisely as I have been instructed by the staff of CHR. I also understand that, once administered, these medications will require close monitoring by blood tests and ultrasound at a frequency, which will be determined by CHR staff, based on clinical needs. This monitoring, and my reliable participation in it, is essential for the safe administration of these medications.

I hereby confirm that I have been advised that CHR staff is available 24 hours, seven days a week to consult on any questions that may arise in regards to the administration of these medications and/or any emergency situation. I have received detailed information on how to contact CHR staff in emergency situations outside of regular business hours and also have received instructions on how to retrieve my daily monitoring results from a confidential telephone mail box, specifically dedicated to me.

I acknowledge that the administration of fertility enhancing medications represents a dynamic clinical situation, with various medications, by different manufacturers, entering and leaving the market. In addition, based on newly published scientific information, medication protocols may change and different medication protocols may be used in different patients, based on their specific clinical circumstances, as determined to the best of their clinical abilities, by the physicians at CHR.

All medications, used at CHR for routine clinical care, are approved by the Food and Drug Administration (FDA).

I also acknowledge that I was given the opportunity to ask all the questions, I wanted to ask, about the use of fertility enhancing medications. Being fully aware of the benefits and risk of fertility enhancing medications, I hereby give my consent to their administration. I understand that I may withdraw this consent at any time.

Signatures on next page:

Date	Signature of Patient	Patient's name (print)
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As one of the staff members of CHR, I hereby confirm that this consent was read, discussed and signed in my presence.

Date	Signature of Witness	Witness' name (print)
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***In New York State doing business as the Medical Offices for Human Reproduction Revised 12/12/05**