

THE CENTER FOR ADVANCED REPRODUCTIVE SERVICES

CONSENT FOR IN VITRO FERTILIZATION AND EMBRYO TRANSFER

Female Name: _____ Female ID# _____

Partner Name: _____ Partner ID # _____

Address: _____

We (I), the undersigned, request, authorize and consent to the performance of the procedure of in vitro fertilization and embryo transfer (IVF/ET) by The Center for Advanced Reproductive Services, PC (The Center), and, as appropriate, its employees, contractors, and consultants and authorized agents.

A. The following is a general outline of the steps that may be required in this procedure. We (I) consent to the performance of these steps:

1. Complete history and physical examination.
2. Medications including but not limited to gonadotrophins, GNRH agonists, GNRH antagonists, and hCG, to mature eggs. We (I) will sign a separate consent for the use of these medications.
3. The use of blood tests to monitor hormone levels.
4. Ultrasound examinations of the ovaries to monitor growth of the developing follicles. Ultrasonography is a diagnostic procedure using sound waves that provides a 'picture' of the ovaries and the growing follicles. No known risks have been associated with this procedure.
5. Providing a sperm specimen and preparation of the specimen for use in the fertilization procedure.
6. Undergoing ultrasound guided transvaginal egg retrieval, which involves insertion of a needle, through the vaginal wall, into the ovary (ovaries) to obtain the eggs.
7. For IVF/ET, placing the eggs and the sperm together in a dish with culture medium to allow fertilization to occur. After 48-144 hours in culture, if there is evidence of normal fertilization and embryo development continues normally, transferring the embryo (or embryos if more than one has developed) into the uterus by means of a small tube inserted through the cervix.
8. For intracytoplasmic sperm injection (ICSI), insertion of an individual sperm into the egg using micromanipulation techniques and equipment.
9. For selective assisted hatching, opening a small hole in the zona pellucida (outer shell) of the developing embryo prior to embryo transfer.
10. The use of intramuscular or vaginal progesterone to maintain the uterine lining. Early reports suggested a possible association between birth defects and the use of synthetic progestins. The progesterone utilized in this procedure is naturally occurring and is similar to that which is normally produced by the ovary; there is no evidence to date of an increased risk of birth defects, but we cannot guarantee that a future link will not be found.
11. The utilization of antibiotics to reduce the risk of infection.
12. The utilization of corticosteroids to increase the likelihood of pregnancy.
13. A blood pregnancy test will be performed approximately 2 weeks after the embryo transfer to determine if pregnancy has occurred.

B. If numerous eggs are obtained, the number exposed to sperm will be decided upon by us (me) and our (my) physician. We (I) may elect to donate the extra eggs (only with our (my) separate informed written consent) if we (I) choose not to expose all of the eggs to sperm. We (I) understand that some non-viable eggs and embryos may be used as a teaching aide for laboratory personnel and then discarded. We (I) understand that non-viable eggs and embryos will be discarded according to ASRM Ethical Guidelines.

Other non-viable eggs, sperm and tissue such as follicular fluid and granulosa cells that would otherwise be discarded could be de-identified and utilized for research purposes based upon our (my)

choices below. This research will not include experiments involving fertilization or the creation of embryos.

- No, we (I) do not wish to donate our (my) discarded non-viable eggs or tissue to research.

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- Yes, we (I) do wish to donate our (my) discarded non-viable eggs, sperm or tissue (limited to but not excluding follicular fluid and granulosa cells) that have been de-identified for current and future research. I understand that any research conducted with our (my) tissue must be approved by a research ethics committee.

Female's Initials _____

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- C. If we (I) elect to expose all of the eggs to sperm in order to develop as many embryos as possible, all viable embryos will either:
1. Be transferred into the uterus or
 2. Cryopreserved

Cryopreserved embryos may be used in the future for our further attempts at conception, or may be:

1. Donated to another couple or woman for their (her) attempts to conceive.
2. Disposed of according to American Society of Reproductive Medicine (ASRM) Ethical Standards
3. Transferred to another fertility center or long term storage facility

Cryopreservation, donation or disposal of embryos will occur only with our (my) written informed consent during the five year maximum storage period.

- D. **Blastocyst Culture** involves placing embryos into culture in the laboratory for additional days to observe their continued development prior to freezing or transfer. The literature indicates that this technique may be useful in selecting the most viable embryos, resulting in transfer of fewer embryos with a corresponding reduction in the risk of multiple pregnancies. In some cases, one or more of the embryos may cease their development prior to reaching the blastocyst stage. This may result in fewer embryos for transfer and, in some cases, no embryo transfer at all. We (I) acknowledge that we (I) have discussed the possibility of the need for this procedure with our (my) physician and understand and agree that it will be utilized based on the best medical judgment of the Center staff at the time of our (my) procedure. We (I) understand that we (I) will be notified if blastocyst culture is performed.
- E. **Intracytoplasmic Sperm Injection (ICSI)** may be used for individuals in whom fertilization capacity may be reduced due to male factor infertility, in situations where previous IVF cycles (utilizing conventional insemination techniques) have resulted in poor fertilization rates, where fertilization did not occur, or in some cases of unexplained infertility, where the potential of the sperm to fertilize an egg may be compromised. Male factor may be indicated by abnormal semen parameters, such as reduced sperm count, motility or normal morphology, on previous semen exams or on the sample provided at the time of the IVF procedure. In some cases, the insertion of a single sperm into the egg, using the micromanipulation techniques of ICSI, can overcome a fertilization defect but may damage the genetic materials. In situations where male factor is the result of a genetic defect, the procedure may permit fertilization to occur normally but the genetic defect may be passed on to resulting

offspring. Therefore, there is an theoretical increased risk of chromosomal abnormalities in children resulting from ICSI.

There are risks associated with the ICSI technique. Mature oocytes (eggs) are required to perform ICSI. If none are retrieved, ICSI may not be possible. Eggs may be retrieved but viable sperm may not be available for use in ICSI. The ICSI procedure may damage or destroy one or more eggs. ICSI may result in fertilization, but subsequent embryo development may not occur. . We (I) understand that the decision to utilize ICSI does not guarantee fertilization.

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: (Please check either OPTION ONE, OPTION TWO, or OPTIONS TWO and THREE. BOTH PARTNERS SHOULD INITIAL):

- Option 1: ICSI will be** used in conjunction with our (my) IVF cycle based upon our (my) treatment plan.

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- Option 2 : ICSI will not** be used in conjunction with our (my) IVF cycle based upon our (my) treatment plan.

Note: *Unless Option 3 is checked in conjunction with Option 2, ICSI will not be utilized under any circumstances.* We (I) understand that as a result of the decision to not use ICSI under any circumstances, fertilization may not occur and an embryo transfer and/or pregnancy may not result.

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- Options 3:** Although we (I) have chosen Option 2, we (I) understand that if semen sample(s) at time of egg retrieval are sub-optimal, based on the best medical judgment of the Center staff, **ICSI may be** used in conjunction with our (my) IVF cycle, despite any previous directive of ours (mine) to the contrary. We (I) understand that we (I) will be notified if ICSI is performed. (Option 3 must be chosen in conjunction with Option 2).

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- F. **Selective Assisted Hatching** may be used in situations where the zona pellucida (the outer shell surrounding the embryo) is abnormally thick. This condition may compromise the ability of the embryo to implant in the uterine wall. Criteria for performing selective assisted hatching include appearance of the embryo and zona pellucida, age of the woman, advanced maternal age where a thickened zona is commonly seen, basal day 3 FSH levels and previous medical history. Literature suggests that the procedure may benefit older women, those with elevated day 3 FSH levels and some cases of unexplained infertility. This procedure (which must be performed on day 3 following egg retrieval) involves opening a small hole in the zona pellucida using micromanipulation techniques.

There are risks associated with this technique. Embryos may be damaged during the process, reducing the number of embryos available for transfer. Despite the use of assisted hatching, implantation may not occur.

We (I) acknowledge that we (I) have discussed the possibility of the need for the selective assisted hatching procedure with our physician and understand, agree and consent that (PLEASE CHECK ONE AND BOTH PARTNERS SHOULD INITIAL):

- Selective Assisted Hatching** may be utilized based on the best medical judgment of the Center staff at the time of the procedure. We (I) understand that we (I) will be notified if assisted hatching is performed.

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- Selective Assisted Hatching** may *not* be used in conjunction with our (my) IVF cycle. We (I) understand that, as a result of this decision, pregnancy may not result.

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- G. Transfer of multiple embryos can result in multiple pregnancy (twins, triplets or more), with an increased risk of miscarriage, premature labor and premature birth. A premature delivery may jeopardize the life and long term health of a child and may result in substantial costs both financially and emotionally.
- H. Pregnancies with more than one baby in the uterus may also increase the occurrence of pregnancy related medical complications for the mother such as high blood pressure and diabetes. Multiple pregnancy also increases the likelihood that a cesarean section will be required.
- I. We (I) understand that the Center follows the American Society of Reproductive Medicine (ASRM) "Guidelines on the Number of Embryos Transferred". According to these guidelines, the number of embryos transferred, in each case, will be determined in consultation with the physician, based on our (my) individual circumstances.
- J. **EMBRYO FREEZING (Cryopreservation)**. We (I) have been informed that if our (my) IVF cycle results in more viable embryos than may be transferred according to Paragraph G above, then the extra embryos will be frozen and stored for our (my) use in the future.

We (I) acknowledge that we (I) have discussed the possibility of the need for the embryo freezing with our (my) physician and understand, agree and consent that (PLEASE CHECK ONE AND BOTH PARTNERS SHOULD INITIAL):

- Embryo Freezing (Cryopreservation)** may be utilized based on the best medical judgment of the Center staff at the time of the procedure. We (I) understand that we (I) will be notified if embryo freezing is performed. We (I) understand that we (I) must execute a separate informed consent for Embryo Freezing (Cryopreservation) and Storage.

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- Embryo Freezing (Cryopreservation)** may *not* be used in conjunction with our (my) IVF cycle. We (I) acknowledge that we have been offered the option to have our (my) extra embryos frozen for our (my) future use but decline that option. We (I) understand that, as a result of this decision, sperm will only be added to the number of oocytes (eggs) that correspond to the maximum number of embryos that we (I) will accept for transfer and the remaining unfertilized oocytes will be discarded. We (I) understand that fertilization and/or embryo development may not occur in all of the oocytes to which sperm is added. We (I)

further understand that this may result in a decreased number of embryos, or no embryos, available for transfer and in a reduced probability of a pregnancy.

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- K. There are a number of reasons IVF/ET may be unsuccessful:
1. Inadequate egg development may result in cancellation of the cycle prior to egg retrieval.
 2. Ovulation may occur spontaneously before the eggs can be retrieved.
 3. In rare cases, no eggs may be retrieved.
 4. The eggs may not be normal.
 5. A fresh semen sample may not be able to be produced the day of the procedure; a frozen specimen (if previously provided) will then be utilized, however, this may result in fewer eggs being fertilized.
 6. Fertilization may not occur, or may occur abnormally, e.g. an egg may be fertilized by more than one sperm (polyspermy) and could develop abnormally. Fertilization may not occur or abnormal fertilization may occur, even with the use of intracytoplasmic sperm injection. Such embryos will not be transferred.
 7. Intracytoplasmic sperm injection may result in damage, destruction or loss of one or more eggs (oocytes) or sperm.
 8. Cleavage or cell division of fertilized eggs may not occur.
 9. The embryos may not develop normally.
 10. Selective assisted hatching may lead to damage or loss of one or more embryos.
 11. The embryo transfer may be difficult or may not be possible.
 12. Implantation of the embryos into the wall of the uterus may not occur, even with the use of selective assisted hatching.
 13. An event may occur in the laboratory resulting in loss or damage to some or all of the eggs or embryos. We (I) understand that we are not entitled to financial compensation should such an accident occur. The program will account honestly for all gametes and embryos.
- L. Although pregnancy may be successfully established, there is still the possibility of miscarriage, ectopic pregnancy, stillbirth and/or congenital abnormalities (birth defects). Conceptions resulting from ART have been associated with a slightly higher risk of congenital anomalies than pregnancies resulting from a natural conception. However, it is still unclear whether the risk is related to patients, medications, or laboratory procedures. It is possible that infertile couples differ from the general population, and it is not the technology that leads to the higher risk.
- M. The following are risks and discomforts associated with this procedure:
1. Blood drawing and medication injections- mild discomfort and a risk of developing a bruise at the needle site.
 2. Medication- the possible development of hyperstimulation of the ovaries which may cause discomfort because more than one follicle is growing; this may result in ovarian enlargement requiring therapy including hospitalization and possible surgery with removal of an ovary (see consent for superovulation therapy).
- Cyst formation-* The medications described above may result in large cysts forming on the ovaries. In the majority of cases, ovarian cysts induced by gonadotropin stimulation disappear spontaneously requiring no intervention. In very rare instances (less than 1% of cycles) these cysts could result in significant abdominal discomfort which could result in the need for hospitalization for observation purposes. One of these cysts could rupture requiring emergency surgery to stop bleeding. This could result in a need for blood transfusions and possible loss of one or both ovaries (0.1% of cycles).
- Fluid shifts-* Fluid shifts within the body may require hospitalization for observation and treatment (1%-3% of cycles). The high levels of estrogen associated with the use of these medications may alter the way

in which the body handles fluids. More specifically, the blood vessels may become “leaky” resulting in the accumulation of fluid within the abdominal cavity (ascites) or around the lungs (pleural effusion). This accumulation of fluid may result in abdominal distension and discomfort with associated shortness of breath (due to the diaphragm being pushed upward by the accumulation of fluid in the abdomen). In severe cases, removal of this fluid from the abdomen or from the space around the lungs may be required using a small needle (0.5% of cycles). The “leaky” vessels may also result in the individual becoming dehydrated because the fluid is in the wrong place, i.e. in the abdomen instead of in the blood vessels. Intravenous fluid administration may be required to maintain adequate blood flow to vital organs such as the kidneys. Severe dehydration could result in irreversible organ failure or blood clot formation leading to a pulmonary embolus (blood clots in the lung) or stroke (less than 0.1% of cycles). There are extremely rare reports in the literature of death occurring as a result of complications of OHSS. **OHSS is a risk that is inherent to ovulation induction therapy; prevention cannot be guaranteed.** At times, when monitoring shows that the risk of OHSS is unacceptably high, a cycle may be canceled. Severe OHSS will rarely occur if hCG administration is withheld.

3. Egg retrieval-
 - a) Possibility of bleeding, infection, or injury to the abdominal organs that may require immediate major surgery possibly resulting in loss of the uterus and/or ovaries, hospitalization for intravenous antibiotic therapy, blood transfusion or, in rare cases, death.
 - b) Moderate discomfort after the procedure.
 - c) The risks associated with anesthesia including nausea, difficulty breathing, respiratory distress or arrest.
 4. Laboratory procedures- the growth of human embryos requires a source of protein. The Center may use a protein product derived from human blood. The manufacturing process involves several purification steps including heat treatment, treatment with detergents, and treatment with ethanol which is thought to render these products free of infectious disease agents such as the hepatitis virus and the virus responsible for AIDS. These blood products are used to treat up to 1 million patients every year for shock, burns, and many other medical emergencies. These products are thought to be extremely safe due to the screening and purification procedures utilized, however, there is a theoretical risk that the agents responsible for causing various infectious diseases could still be transmitted by utilization of these blood derived products.
 5. The utilization of medications at the time of egg retrieval and embryo transfer-
 - a) Utilization of antibiotics may result in an allergic reaction, which may result in a rash. In its most severe form, an allergic reaction may be life threatening. The utilization of tetracycline/doxycycline is associated with an increased sensitivity to the sun and, therefore, caution should be taken to avoid prolonged sun exposure. The utilization of antibiotics may also be associated with nausea, vomiting, diarrhea, loss of appetite and vaginal yeast infections.
 - b) Utilization of corticosteroids may be associated with mood changes, insomnia, gastrointestinal disturbances, masking of the signs of infection, interference with the metabolism of carbohydrates and vaginal yeast infections.
 - c) Utilization of intramuscular progesterone may be associated with soreness, swelling and infection at the site of injection.
 6. Embryo transfer-
 - a) Discomfort, risk of developing infection and possible bleeding.
 - b) A multiple pregnancy (twins, triplets or more) may occur even if only one embryo is transferred.
 - c) A pregnancy may implant outside of the uterus, in a fallopian tube (ectopic pregnancy) or elsewhere and require surgery for treatment.
 7. Psychological stress.
- N. Insurance coverage for any or all of the above procedures may not be available and we (I) will be personally responsible for all expenses of this treatment which are not covered by insurance.

- M. We (I) understand the confidentiality of medical records, including any photographs, X-rays or recordings, will be maintained in accordance with applicable state and federal laws. We (I) may request our records be released to other physicians. Data from your ART procedure will also be provided to the Centers for Disease Control and Prevention (CDC). The 1992 Fertility Clinic Success Rate and Certification Act requires that CDC collect data on all assisted reproductive technology cycles performed in the United States annually and report success rates using these data. Because sensitive information will be collected on you, CDC applied for and received an “assurance of confidentiality” for this project under the provisions of the Public Health Service Act, Section 308(d). This means that any information that CDC has that identifies you will not be disclosed to anyone else without your consent.
- N. We (I) expect this procedure to be performed with not less than the customary standard of care. We (I) understand the risks and benefits as outlined, and further understand and agree that The Center shall be responsible only for acts of negligence on its part and the part of its employees, contractors, and consultants and authorized agents.
- O. We (I) understand that the program does not guarantee a pregnancy or a successful pregnancy. We (I) have discussed the program’s current success rates with our physician.
- P. We (I) have had the opportunity to review this treatment and ask questions of our (my) physician concerning alternatives to IVF, including adoption and no treatment.
- Q. **We (I) represent, agree and acknowledge that we (I) are (am) not married to individuals who are not parties to this informed consent.**
- R. The nature of IVF/ET has been explained to us (me), together with the known risks. We (I) understand the explanation that has been given to us. We (I) have had the opportunity to ask any questions we (I) might have and those questions have been answered to our (my) satisfaction. Any further questions may be addressed to The Center staff or IVF/ET Program Director, Dr. John Nulsen at (860) 679-4580. We (I) acknowledge that IVF/ET is being performed at our (my) request and with our (my) consent.

