Consent for In Vitro Fertilization and Embryo Transfer

We (I), the undersigned, request, authorize and consent to the performance of the procedure of in vitro fertilization and embryo transfer (IVF/ET) by Sanford Clinic North, doing business as Sanford Reproductive Medicine (Sanford), 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. Undergoing complete history and physical examination.
   2. Taking medications including but not limited to gonadotrophins, GNRH (Gonadotropin Recombinant Hormone) agonists, GNRH antagonists and hCG (human Choriogonadotropin), to mature eggs. We (I) will sign a separate consent for the use of these medications.
   3. Undergoing blood tests to monitor hormone levels.
   4. Having 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 progesterone to maintain the uterine lining. 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 to 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 cryopreserve all unfertilized oocytes and fertilize them at a later date. 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 non-viable eggs will be discarded according to the American Society of Reproductive Medicine (ASRM) Ethical Guidelines. 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. Transferred to another Reproductive Medicine or long term storage facility

Cryopreservation or donation will occur only with our (my) written informed consent during the one year maximum storage period.

C. **Intracytoplasmic Sperm Injection (ICSI)** may be used for individuals in whom fertilization capacity maybe reduced due to male factor infertility, in situations where previous IVF cycles (utilizing conventional insemination techniques) 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 a 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) 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 ON AND BOTH PARTNERS SHOULD INITIAL):

- ICSI may be utilized based on the best medical judgment of Sanford Reproductive Medicine (Sanford) staff at the time of our (my) procedure. We (I) understand that we (I) will be notified if ICSI is performed.
  - Female’s Initials_________________________
  - Partner’s Initials_________________________

- ICSI may not be used in conjunction with our (my) IVF cycle. We (I) understand that, as a result of this decision, fertilization may not occur and an embryo transfer and/or pregnancy may not result.
  - Female’s Initials_________________________
  - Partner’s Initials_________________________

D. **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. 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 assisted hatching procedure with our physician and understand, agree and consent that (PLEASE CHECK ONE AND BOTH PARTNERS SHOULD INITIAL):
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☐ Assisted Hatching may be utilized based on the best medical judgment of Sanford Reproductive Medicine (Sanford) staff at the time of the procedure. We (I) understand that we (I) will be notified if assisted hatching is performed.
  Female’s Initials____________________
  Partner’s Initials___________________

☐ 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.
  Female’s Initials____________________
  Partner’s Initials___________________

E. 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. 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.

F. We (I) understand that Sanford Reproductive Medicine (Sanford) 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.

EMBRYO or OOCYTE 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 F above, then extra embryos will be cryopreserved for our (my) use in the future.

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

☐ Embryo or Oocyte Freezing (Cryopreservation) may be utilized based on the best medical judgment of Sanford Reproductive Medicine (Sanford) 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 or Oocyte Freezing (Cryopreservation) and Storage.
  Female’s Initials____________________
  Partner’s Initials___________________

☐ 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 understand that we have another option in this case (Please initial):
  1. We (I) understand that, as a result of this decision, sperm will be added to a maximum of four oocytes (eggs) and we (I) will accept transfer of all resulting embryos. The remaining unfertilized oocytes will be discarded or frozen, depending on our preference. Freezing of unfertilized oocytes (eggs) requires a separate consent. 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 pregnancy.
    Female’s Initials____________________
    Partner’s Initials___________________
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G. 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 (polyspermia) 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 because they have arrested and became non-viable.
10. Selective assisted hatching may lead to damage or loss of one or more of the 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.

H. Although pregnancy may be successfully established, there is still the possibility of miscarriage, ectopic pregnancy, stillbirth and/or congenital abnormalities (birth defects). It does not appear that this procedure has any greater risk of producing an abnormal child than does a pregnancy resulting from a natural conception.

I. 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.)
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. Sanford Reproductive Medicine (Sanford) 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.
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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 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 when 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.


J. 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.

K. We (I) understand and agree that the confidentiality of medical record, including any photographs, X-rays or recordings, will be maintained in accordance with applicable state and federal laws. Federal law requires that data concerning IVF cycles are released to the Centers for Disease Control Prevention (CDC) for external auditing. This data reporting may include identifying information. We (I) may request that our records be released to other physicians.

L. We (I) understand and agree that data from our (my) ART (assistive reproductive technologies) 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 this data. Because sensitive information will be collected on us (me), CDC applied for and received an “assurance of confidentiality” for the project under the provisions of the Public Health Service Act, Section 308(d). This means that any information that CDC has that identifies us (me) will not be disclosed to anyone else without our (my) consent.

M. We (I) understand and agree that pregnancy and birth of a child or children may result from our (my) participation in treatment and services at Sanford Reproductive Medicine (Sanford). We (I) understand and agree that Sanford cannot advise us (me) about the legal relationships or obligations that will result from a pregnancy or birth from participation in these services. We (I) understand and agree that we (I) should consult with an attorney of our (my) own choice to determine our (my) legal rights and obligations regarding any pregnancy or birth resulting from participation in these services. We (I) release, indemnify, and hold harmless Sanford, its employees, contractors, consultants, and authorized agents from any and all liability, costs, expenses and attorneys’ fees regarding our (my) legal rights and obligations regarding a pregnancy or birth which occurs from participation in this program. We (I) voluntarily consent to participation in these services and to the legal rights and obligations that result.
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N. We (I) understand that compliance with recommendations of the Sanford Reproductive Medicine (Sanford) is necessary to optimize the chances for successful treatment. We (I) agree to comply with those requirements. We (I) also understand that some tests, studies or procedures which are part of this treatment must be performed at Sanford Reproductive Medicine or another qualified Reproductive Medicine Department. Those requirements have been discussed with us (me) and we (I) agree to follow them. We (I) understand and agree that if we (I) do not follow recommendations of Sanford or comply with requirements for treatment, Sanford may elect to discontinue our (my) participation in treatment or services at Sanford Reproductive Medicine. If our (my) participation is discontinued for this reason, we (I) agree that Sanford will have no liability or further obligation to us.

O. 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 Sanford Reproductive Medicine (Sanford) shall be responsible only for acts of negligence on its part and the part of its employees, contractors, consultants and authorized agents.

P. 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.

Q. We (I) have had the opportunity to review this treatment and as questions of our (my) physician concerning alternatives to IVF, including adoption and no treatment.

R. We (I) represent, agree and acknowledge that we (I) are (am) not married to individuals who are not parties to this informed consent.

T. 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 Sanford Reproductive Medicine (Sanford) staff or Dr. Steffen Christensen, Medical Director. We (I) acknowledge that IVF/ET is being performed at our (my) request and with our (my) consent.

Date:______/______/______  ______________  ________________________________     ________________________________
Time          Female Signature          Witnessed By

Date:______/______/______  ______________  ________________________________     ________________________________
Time        Partner Signature           Witnessed By

Note: Each Signature Must Be Witnessed Separately.

Physician Signature:

This consent has been read by and discussed with the patient and her partner, if any.

Date_______/_______/_______   _______________________________   ______________________________________________________________
Time         Physician Signature